

VISION SCREENER



USER MANUAL VISIOLITE® FLEX



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1. Introduction

The Visiolite® Flex is intended for the evaluation of visual function and the screening of visual impairments.

The **important symbols** used in these instructions are shown below:



WARNING: Indicates conditions or practices which, if not avoided, can cause danger to the patient and user and/or environment.



CAUTION: Indicates conditions or practices that could result in damage to the equipment.



NOTE: Indicates important information about the use of the device.

2. Instructions for your safety



WARNING: Do not disassemble the device or work on internal components.

WARNING: Do not open the device or insert any object into it.

WARNING: Do not use any power supply or accessories other than those provided with the device, as this may compromise its performance and safety.



CAUTION: Do not store or use the device outside the environmental conditions specified in the technical characteristics.

CAUTION: Do not immerse the device in liquid or expose it to spraying.

CAUTION: Do not use the device if it shows any visible signs of damage.

3. Clinical information

Intended use

The Visiolite® Flex is intended for the evaluation of visual function and the screening of visual impairments.

Device users



CAUTION: The Visiolite® Flex must only be used by health professionals (doctor, nurse, optometrist, ophthalmologist, optician, medical secretary, etc.) or by persons who have received training in conducting optical examinations, who have undergone recognized and complete training in the use of the device by FIM Medical or one of its approved partners.

Test results must always be communicated with appropriate medical interpretation.

The Visiolite® Flex must not be used to establish a medical prescription and must never be used as the basis for a medication prescription or a pre- or post-surgical diagnosis. Only an ophthalmologist can confirm and corroborate the results obtained with the Visiolite® Flex by other examinations in order to prescribe a correction or surgical intervention.

Patient population

The Visiolite® Flex is designed for visual acuity testing in patients older than 3 years who are able to understand and follow instructions, and whose pupillary distance matches the lens dimensions.

Contraindications

Glare tests with the Visiolite® Flex should not be performed on patients who are photosensitive, have recently taken photosensitizing medications (examples listed in Table 1), have undergone eye surgery or experienced ocular trauma within the past 3 months, or suffer from any of the following conditions: albinism, cystinosis, keratoconjunctivitis, or ocular inflammation.

If there is any doubt, medical advice is essential before conducting a glare test.

If the patient experiences discomfort or eye pain, the test must be immediately discontinued.

For photosensitive patients, a low photopic mode can be used.

Table 1: *Non-exhaustive list of examples of photosensitizing drugs*

Antibiotics	Antifungals	Antidepressants
Doxycycline Ciprofloxacin Levofloxacin Sulfamethoxazole	Griseofulvin Voriconazole	Amitriptyline Imipramine Sertraline
Antihistamines	Non-steroidal anti-inflammatory drugs	Diuretics
Diphenhydramine Promethazine	Ibuprofen Naproxen Piroxicam	Hydrochlorothiazide Furosemide
Cardiovascular drugs	Psychotropic drugs	Antidiabetic drugs
Amiodarone Nifedipine Quinidine	Chlorpromazine Thioridazine	Glipizide Glibenclamide or glyburide

Limitations of use

This device cannot be used if the patient is unable to understand and follow the test.

The equipment works on the basis of binocular fusion. The operator must ensure that the patient has sufficient fusion to carry out the examination.

Before any examination, the patient should be asked if he or she usually wears optical correction.

For photosensitive patients, the light level can be reduced at any time during the examination.

The examination should be carried out in an appropriate environment, ensuring that the patient is not disturbed by a light source external to the device.

In the case of a glare test, the operator / user must inform the patient of the test procedure and ensure that there is no persistent discomfort at the end of the test.

Once the test is completed, the operator/user must clean the device, especially the parts that come into contact with the patient.

Clinical benefits

The performance and variety of the visual tests offered by the Visiolite® Flex provide an indirect qualitative clinical benefit by helping to screen patients for various visual disorders.

Adverse effects and potential side effects

The Visiolite® Flex does not generate adverse effects or side effects related to its use.

4. Technical description

Materials provided

Equipment included with the Visiolite® Flex device:

- A visual system to display the test to the patient
- A power supply
- A USB cable for connecting to a computer to control the device

Table 2: Visiolite® Flex configuration

Aspect	Computer	Network	Wired Remote
Access Type	Local software / USB	Remote Server / Ethernet	Embedded software / USB
Supported Configurations	Full settings, operability & DB management	Shared settings, user rights, centralized DB	Limited settings, full operability, no patient DB
Advanced Features	License control, multi-device sync	Multi-device deployment, audit trail	Direct test control

The Visiolite® Flex integrates:

- **Display Unit** with adjustable luminance to reproduce photopic or mesopic light conditions,
- **Optical system** to simulate different distances enabling realistic testing from near to far vision,
- **Controlled dark environment** to ensure that light from the display or integrated light sources is the only visual stimulus perceived by the patient,
- **LED** to emit light spots and simulate peripheral stimuli for visual field test or glare situations,
- **Housing** with integrated forehead rest to align the patient's eyes precisely with the optical axis of the display or stimulus projection. The housing has a wraparound shape, partially enclosing the patient's face to block external light,
- **Support** with adjustable height and tilt, designed to best fit the patient's head level,
- **Connectivity:** Equipped with USB, Ethernet, eye-tracking technology, and integration with external medical record systems.

Configuration with computer

The Visiolite® Flex can be used with a computer and desktop software for enhanced data exchange features and integration with other FIM products.

Configuration of the device:

- Visiolite® Flex device with power supply,
- USB cable connecting the Visiolite to the computer for test control and data exchange,
- Computer (laptop or desktop),
- Desktop software to operate the device and **exchange patient data with third-party software.**

Computer-free configuration (Standalone Mode)

The Visiolite® Flex can be used without a computer to best suit simplified or mobile screening setups.

Configuration of the device:

- Visiolite® Flex device with power supply,
- USB-Wired remote control,
- A paper-based answer sheet for manual response collection.

Accessories and synergies with other FIM products:

- Transport trolley for easy mobility

Device presentation

The Visiolite® Flex is a medical device for screening various visual function disorders, such as: refractive errors (ametropia, including hyperopia, myopia, presbyopia, and astigmatism), AMD, diplopia, or dyschromatopsia.

The principle of the device is to display images to the patient (tests). Depending on what the patient perceives, it is possible to detect visual impairments.

The tests assess the patient's visual function at near, intermediate, and far distances, as well as with a hyperopia setting. Different distances are available for each vision depending on the configurations (see optical distances in section 5, Technical characteristics).

Tests can be performed using either monocular (right or left) or binocular vision. Limitations may apply to individual tests.

The Visiolite® Flex also allows visual tests to be carried out at different lighting levels:

- Photopic lighting (160 cd/m² adjustable at the patient's request to 80 cd/m²)
- Mesopic lighting (low brightness of 3 cd/m²)

The device operates in two control modes:

- Autonomous in remote-controlled version
- Interfaced in computerized version

Designed to be as ergonomic as possible, the Visiolite® Flex is equipped with a head presence sensor that detects the position of the patient's forehead. Once the patient is correctly positioned, the examination can begin.

The Visiolite® Flex offers the following advantages:

- Ergonomics of use and transport, in remote-controlled or computerized version
- Speed of startup and execution
- Highly configurable and automatable
- Highly interoperable with major third-party/business software

The examination can be performed independently by the patient using the optional VisioClick® accessory. This automation accessory operates using voice instructions delivered via headphones, to which the patient responds via a push button.



1. Removable forehead rest
2. LED for visual field testing
3. Optics for distance and intermediate vision testing
4. Optics for near vision testing
5. Ergonomic nasal location
6. Location of connectors
7. Location of on/off button
8. VESA clip
9. Stand
10. Base
11. Power supply adapter with interchangeable regional plugs
12. Remote Control

FF1165.MUT.102 V01.00.00 VisioWin® Software V02.01.00

5. Technical characteristics

Features of the Visiolite® Flex

Internal display **Display 2.56" 2k 2160x2160**
Display 2.56" 2k 2160x2160

Backlight type Double (2 x 3 x 6 LED)

Brightness levels Photopic 80 or 160cd/m²
 Mesopic 3 cd/m²

Optical distances The device includes 5 optical distances depending on the setting and two lenses for hyperopia.

EU/DE settings:

Near vision	33cm
Intermediate vision	60cm / 80cm / 1m
Far vision	5m
Hyperopia	+1δ / +1.5δ

US settings:

Near vision	14"
Intermediate vision	24" / 32" / 40"
Far vision	20ft
Hyperopia	+1δ / +1.5δ

UK settings:

Near vision	16"
Intermediate vision	24" / 32" / 40"
Far vision	20ft
Hyperopia	+1δ / +1.5δ

Connectivity	USB Type B 3.0			
Remote touchscreen	TFT-LCD 7” 1024x600	Capacitive touch		
Remote power supply	5V DC / 11W / 2.2A Max			
Power supply unit	Input: 100-230V AC / 50-60Hz / 0.6A	UE Electronic		
	Output: 12V DC / 24W / 2.0 A Max	UES24LCP-120200SPA / Globtek		
	Cable length: 2.99m	GTM41060-2512		
Protection level	Medical electrical equipment – protection according to EN 60601-1			
Electric class	II			
Storage & transport temperature	-10 to 60°C			
Temperature of use	15 to 35°C			
Regulatory standards	ISO 10993-1, EN 62366-1 /A1, EN ISO 15223-1, EN ISO 20417			
Safety standards	ISO 10993-1, EN 60601-1, EN 60601-1-2, IEC 60601-1-6, ANSI Z80.36, EN ISO 15004-2, IEC 62471			
Medical class	Class I (rule 1 and rule 13), Medical Device Regulation (EU) 2017/745, Annex VIII			
EMDN code	Z1212012001 - Visual functional assessment equipment			
GMDN code	65177 - Vision physiology/eye movement analysis system			
Applied part	Forehead rest	Type B		
Dimensions	37 x 26.5 x 32.5 cm	Packaged	34 x 23 x 20 cm	Visual system only
Weight	3.3 kg	Packaged	2 kg	Visual system only

Dimensions and Weight — Visiolite® Flex

Component	State	Dimensions (L x W x H)	Weight
Visual system	Unpackaged	34 x 23 x 20 cm	2 kg
	Packaged	37 x 26.5 x 32.5 cm	3.3 kg
VESA support	Unpackaged	24 x 30 x 39.5 cm	2.5 kg
	Packaged	45 x 28 x 11.5 cm	2.8 kg
Assembled unit, ready to use	Low position	42 x 24 x 42 cm	4.5 kg

Hardware requirements for VisioWin® software

VisioWin® Software	Minimum Configuration	Recommended Configuration
Operating system	Windows 10 version 1809	Windows 11
Processor	Intel Core i3 or equivalent	Intel Core i5 or higher
Architecture	64 bits	64 bits
Memory	4 GB RAM	8 GB RAM
Disk space	16 GB	20 GB
Graphic card	256 MB	512 MB
Monitor resolution	1024x768	1920x1080

VisioClick® specific characteristics

Voltage	5VDC (via USB port)		
Power	2.5W maximum		
Output Impedance	16 Ω - 32 Ω		
Audio Connector	3.5mm stereo TRS jack		
Headset Cable Length	1.2 m		
Frequency Range	20 Hz - 20 kHz		
Medical Class	I		
Software Safety Class	A		
Patient-Applied Part	Headset ear cushion		
Headset Ear Cushion Material	Non-woven polypropylene 35g/m ² , biocompatible		
Weight	0.475kg	Response unit only 0.700 kg	Cable, holder, headset included

6. Symbols

	CE marking according to Medical Device Regulation (EU) 2017/745		Instructions for use
	Type B applied part		Direct current
	Must not be disposed of with unsorted waste, but treated in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive		Manufacturer Identification
	Medical Device		Date of manufacture
	Batch Number		Keep dry
	Serial Number		Fragile
	Storage temperature from -10 to 60°C		This way up
	Unique Device Identifier	(11)XXXXXX	UDI Identification - Date of manufacture
(01)XXXXXXXXXXXXXX	UDI Identification - Unique product identification number	(10)XXXXXX	UDI Identification - Batch number

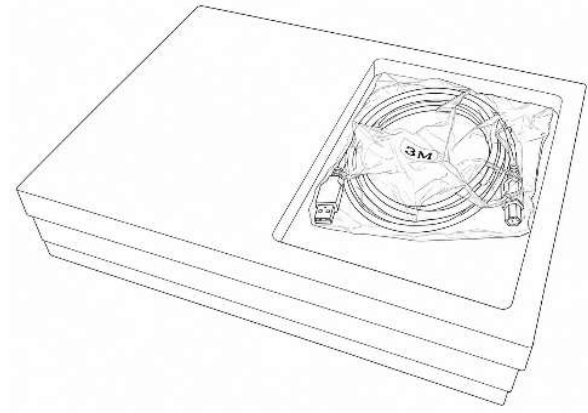
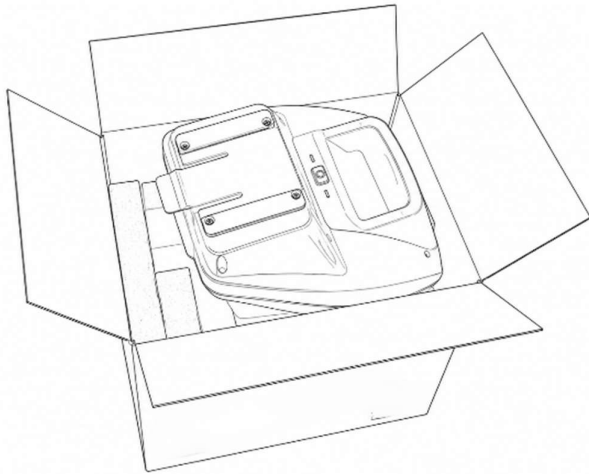
7. Installing the Visiolite® Flex

Unpacking the device



NOTE: Keep the box and cables — they may be needed if the device has to be returned for maintenance or repair.

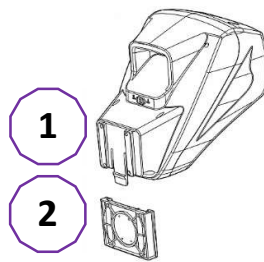
1. Open the box.
2. Remove the compartmentalized foam tray, which contains the USB type A to USB type B cable.
3. Lift the Visiolite® Flex out by the handle to access the power supply adapter with the interchangeable regional plugs



Installing the Visiolite® Flex

Attaching the VESA clip

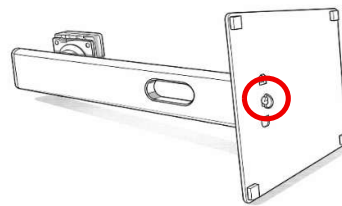
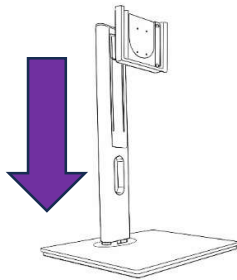
1. Screw the VESA clip onto the back of the device in the dedicated mounting area, as shown in the image below.
2. Screw the VESA clip onto the VESA mount or stand.



Assembling the stand and the base

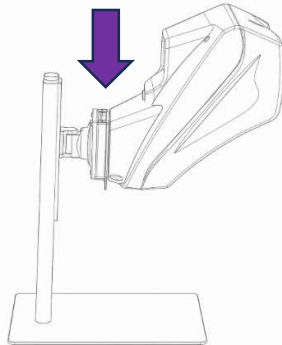
Insert the stand into the base, aligning it with the designated holes.

From underneath the base, use the tightening mechanism (circled in red) to screw and secure the stand to the base.



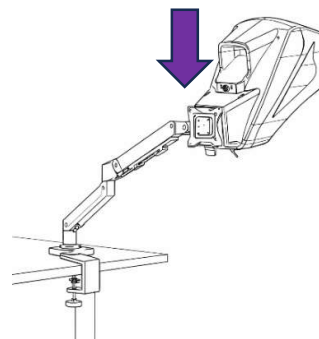
Attaching the Visiolite® Flex to the stand and base

Slide the VESA clip on the device into the VESA clip on the stand until they are securely connected.



Attaching the Visiolite® Flex to a VESA mount

Slide the VESA clip on the device into the VESA clip on the VESA mount until they are securely connected.



Connecting the cables



WARNING: Do not use any power supply or accessories other than those provided with the device, as this may compromise its performance and safety.

	Computerized version	Remote-controlled version
1. LAN (Ethernet) port 2. Power supply connector 3. USB Type-B port	Connect the Visiolite® Flex to the computer using one of the following connection methods: Ethernet connection: Connect the Visiolite® Flex to your local network using an RJ45 Ethernet cable plugged into the LAN (Ethernet) port. USB connection: Connect the Visiolite® Flex to the computer using the supplied USB cable. - Connect the USB Type-B connector to the Visiolite® Flex. - Connect the USB Type-A connector to the computer.	Connect the USB Type-B connector of the remote control cable to the Visiolite® Flex.

Removable forehead rest



WARNING: Follow the cleaning directions for the device and the removable forehead rest mentioned in the Cleaning section to avoid risk of cross-contamination.



CAUTION: If the FIM Medical logo on the removable forehead rest begins to fade, it is recommended to replace the forehead rest.

The box also contains a pouch of spare removable forehead rests.

Before using the device, it is necessary to install the removable forehead rest by inserting it in the dedicated place on the front of the device.



Check that the FIM Medical logo (circled in red) remains clearly visible. Replace the forehead rest if the logo starts to fade.

Computerized version: First start of the VisioWin® installer

The download link for the VisioWin® software is available in the Information Sheet supplied with the device.

Computerized version: Installation of VisioWin® software



NOTE: Administrator rights are required to install VisioWin® software.

NOTE: Copying the installation file this way may take longer than downloading it via the internet.

Run the SetupVisioWin.exe installation file you have retrieved.

Select the language of the installation wizard.

Use of the VisioWin® software is subject to license conditions, which you must read and accept.

If you refuse these conditions within 48 hours of installation, you may return the device.

Enter the license key provided in the Information Sheet supplied with the device.

Select the installation folders for the software and the database.

Once the installation has been completed, the Visiolite® Flex can be used with the VisioWin® software.

8. Preliminary explanations to the patient

Adjusting the device



CAUTION: The Visiolite® Flex must be placed on a flat, stable surface.

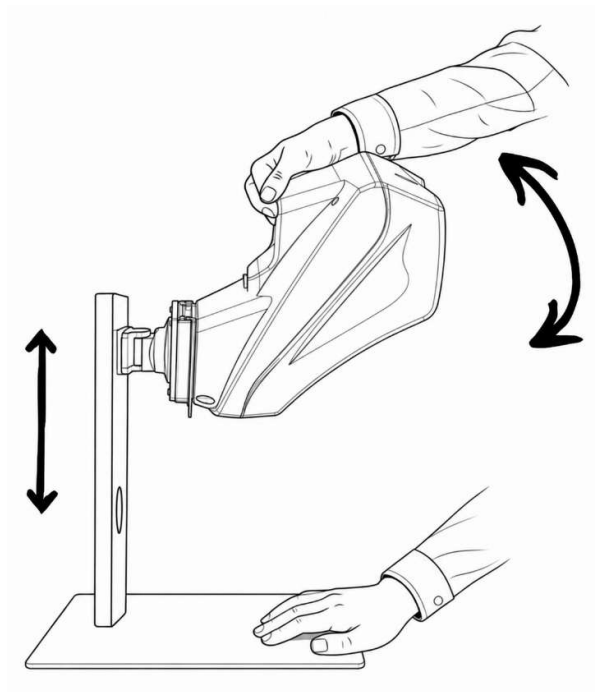
If the device is mounted on a VESA mount, ensure that the mount is placed on a flat, stable surface.

CAUTION: When mounted on the stand and base, the Visiolite® Flex must be transported only after being detached from them.

It is important to check that the patient is in the correct position before starting an examination, as this is the key to a successful examination.

We recommend that the patient sits with his or her back straight, facing the device, and that the device is tilted so that it rests on the forehead.

Before using the Visiolite® Flex with a patient, adjust the height and the inclination while holding the base or the VESA mount if the device is mounted on it.



9. Using the remote-controlled Visiolite® Flex



The remote control allows the user to operate the Visiolite® Flex and perform the examinations without using a computer.

Carrying out a remote-controlled examination

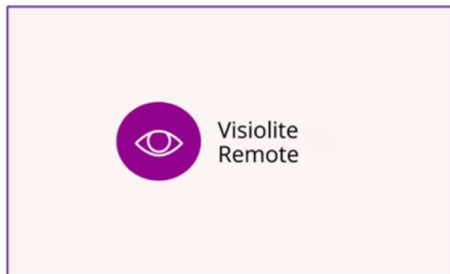
Remote control start

Connect the Visiolite® Flex to the power supply unit and connect the remote control to the Visiolite® Flex using the USB Type B cable.

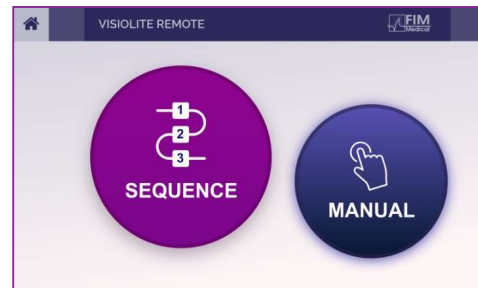
Turn on the remote-controlled Visiolite® Flex using the ON/OFF switch.

The remote control then turns on automatically. A startup screen is displayed while the home page initializes.

The remote control's touch interface then provides access to the various functions.



Remote control startup screen



Remote Control Home Page

Remote control setup

The remote-control settings are accessible via the  button located in the lower left corner of the remote-control home page.

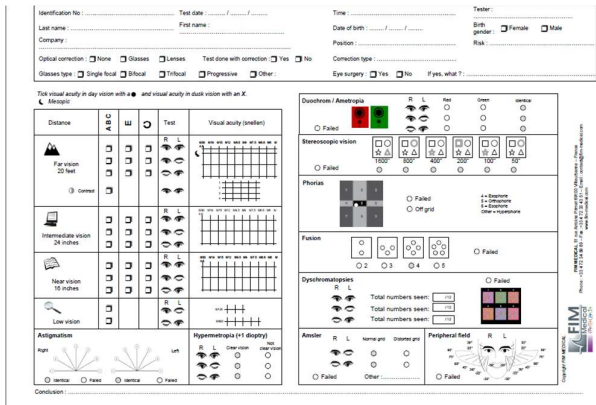
- (1) Choice of interface language.
- (2) Choice of unit for visual acuity results: LogMAR, Tenths, Tenths x10, Snellen 20ft or 6m.
- (3) Enable or disable forehead detection.
If you activate this function, the tests will be displayed on the device only if the patient's forehead is in contact with the forehead support of the Visiolite® Flex.
- (4) Remote control information.



Using the response block

The response block can be downloaded from the link provided in the Information Sheet supplied with the device.

The results of the various tests carried out manually or in sequence can be entered by hand on the response block.



The response block form contains the following sections:

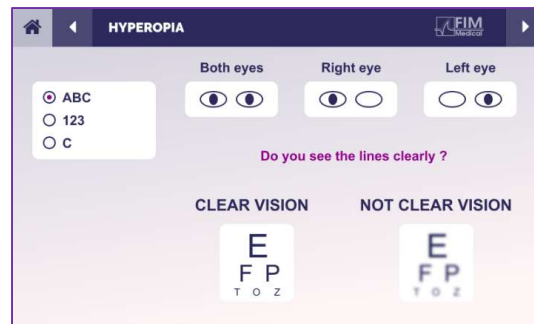
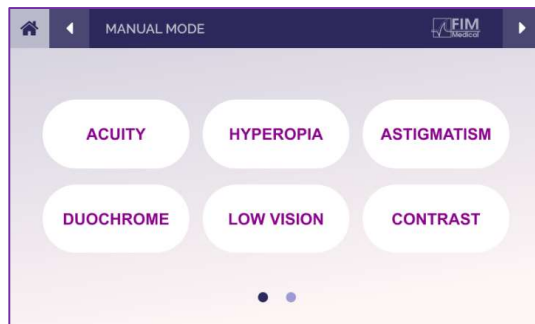
- Identification:** Patient name, date of birth, sex, and contact information.
- Test details:** Test date, time, and location.
- Visual acuity:** Distance (20 feet) and Near (18 inches) vision tests with charts and recording grids.
- Other tests:** Stereo vision, Phoria, Fusion, Divergence, and Anisometropia.
- Conclusion:** A section for the examiner's final assessment.

Using the remote control in manual mode

Manual mode gives access to all the tests available on the remote control.

Select a test and the test conditions via the touch interface to control the slides to be displayed to the patient.

The instruction to be given to the patient is also visible on the test page.

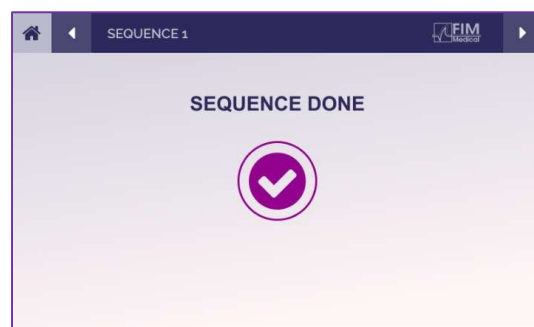
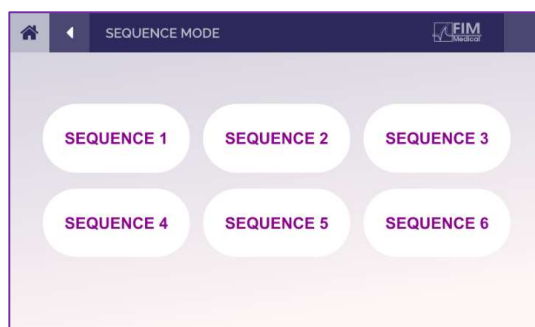


Enter the result perceived by the patient on the response block.

Using the remote control in sequence mode

Sequence mode gives access to all pre-recorded test sequences on the remote control.

Select a test sequence via the touch interface and follow the instruction to be given to the patient.



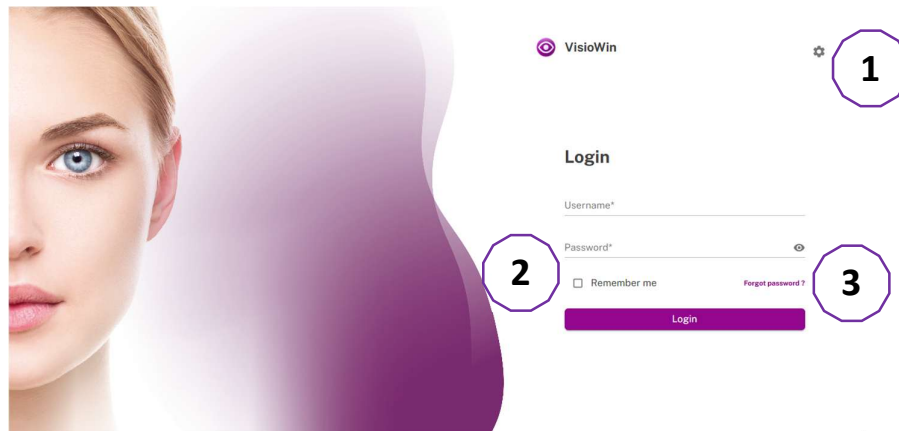
10. VisioWin® Software first connection

When using the VisioWin® software for the first time, you will be prompted to complete the following steps:

Enter the activation key, select your language, and accept the Terms of Use.

Upon launching the software, enter the activation key. This key can be found on the information sheet provided with your device. Then select your preferred language. Please read the General Terms and Conditions of Use (available via the orange link), and accept them to continue.

VisioWin® Software Login Page



1. Interoperability Settings: Settings that ensure communication between VisioWin® and your business software (EMR). This tab is detailed in the Interoperability section of the software settings.
2. Remember Me: Enables automatic login to the operator's session during future uses of the software.
3. Forgot Password: Allows password recovery in case of loss. To create a new password, you will need to answer the security question you defined when creating your account.

← **Forgot Password**

What was the name of your first pet?

Answer*

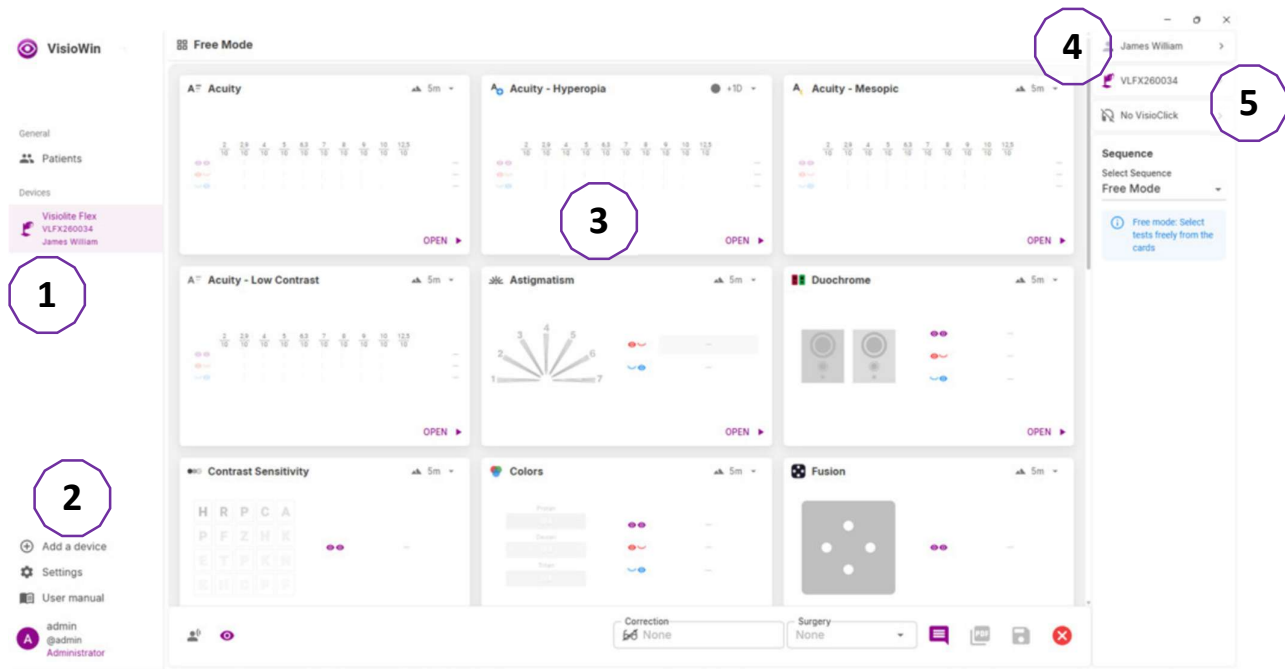
New password* 

Confirm password* 

CONFIRM

11. VisioWin® Software Home page

User interface description



- 1. Navigation menu:** Provides access to the connected vision screener, the examination window, and previous examinations.
- 2. Settings:** Provides access to device management, software settings, the user manual, and the user profile.
- 3. Examination window:** Provides access to the available tests.
- 4. Patient profile:** Allows you to create a new patient profile and/or view the selected patient's information.
- 5. Device information:** Displays the connected device (Visiolite® and/or VisioClick®) along with its associated information.

Description of the icons

	Create new profiles (users, patients, etc.)
	Access settings
	View user manual
	Edit profiles (users, patients, etc.)
	Delete selected profiles (users, patients, etc.)
	User profile
	No device connected
	Device connected
	VisioClick® headset connected
	VisioClick® headset not connected
	The patient's forehead is in contact with the device and is therefore detected.
	The patient's forehead is not in contact with the device and is therefore not detected.
	Patient forehead detection is not activated
	Patient profile of the person undergoing the test.
	List of all patients
	Open test button
	Free Mode
	Sequence Mode
	Eye-tracking disabled
	Eye-tracking enabled

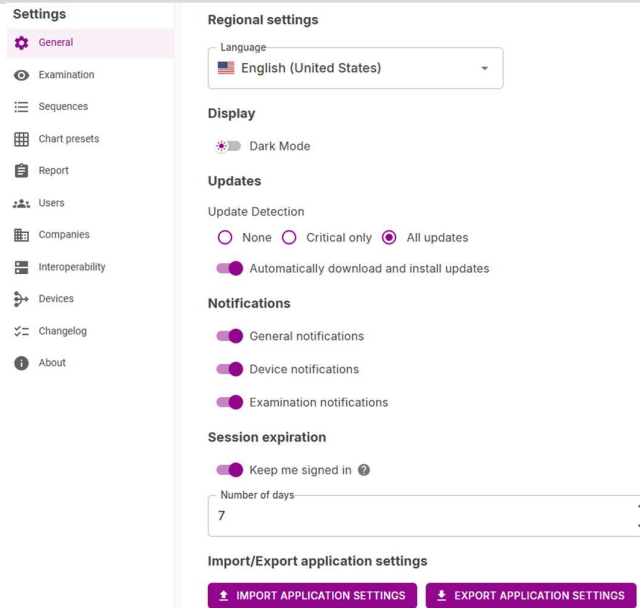
12. VisioWin® Software settings

General



NOTE: If you do not check the "Automatically download and install updates" box, an information window will appear when VisioWin® starts, informing you that an update is available.

NOTE: If you wish to update, you will have to click on the "Update" button that will appear at the top right corner of your VisioWin® software.



The screenshot shows the 'Settings' window with the 'General' tab selected. The left sidebar lists various settings categories: General, Examination, Sequences, Chart presets, Report, Users, Companies, Interoperability, Devices, Changelog, and About. The main content area is divided into several sections:

- Regional settings:** A dropdown menu for 'Language' is set to 'English (United States)'.
- Display:** A toggle switch for 'Dark Mode' is currently turned off.
- Updates:** Under 'Update Detection', the 'All updates' radio button is selected. The 'Automatically download and install updates' toggle switch is turned on.
- Notifications:** Three toggle switches are shown: 'General notifications', 'Device notifications', and 'Examination notifications', all of which are turned on.
- Session expiration:** A toggle switch for 'Keep me signed in' is turned on. Below it, a 'Number of days' dropdown menu is set to '7'.
- Import/Export application settings:** Two buttons are visible: 'IMPORT APPLICATION SETTINGS' and 'EXPORT APPLICATION SETTINGS'.

The general options are divided into 6 sections:

Regional Settings:

Allows you to change the display language.

Display Settings:

Enables you to choose between light mode and dark mode.

Updates:

Allows you to set your preferences for automatic updates of the VisioWin® software.

Notifications:

Choose whether you want to receive notifications from the software, the connected device, or those related to the ongoing examination.

Session Expiration:

Enable or disable session expiration to control whether the user session automatically expires after a period of inactivity, and specify the number of days before the session is terminated.

Import/Export Application Settings:

Import: Allows the operator to import the VisioWin® software parameters.

Export: Allows the operator to export the VisioWin® software parameters.

By default, VisioWin® uses the regional settings of the Windows operating system.

Examination

Settings

General

Examination

Sequences

Chart presets

Report

Users

Companies

Interoperability

Devices

Changelog

About

Distance units

Distance units

Metric (m, cm)

Acuity units

Acuity units

Decimal /10

Custom corrections

Add custom correction types in addition to the built-in defaults

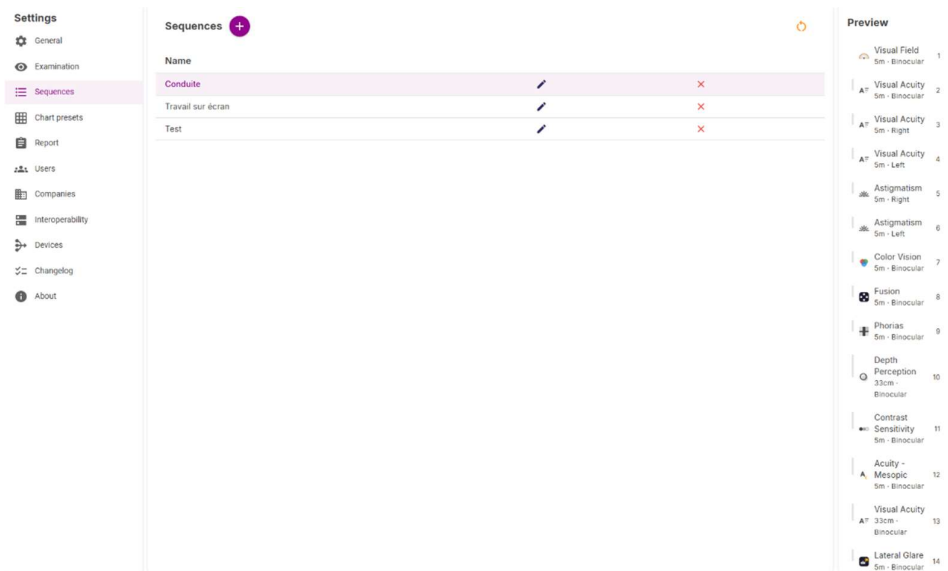
Add a custom correction

+

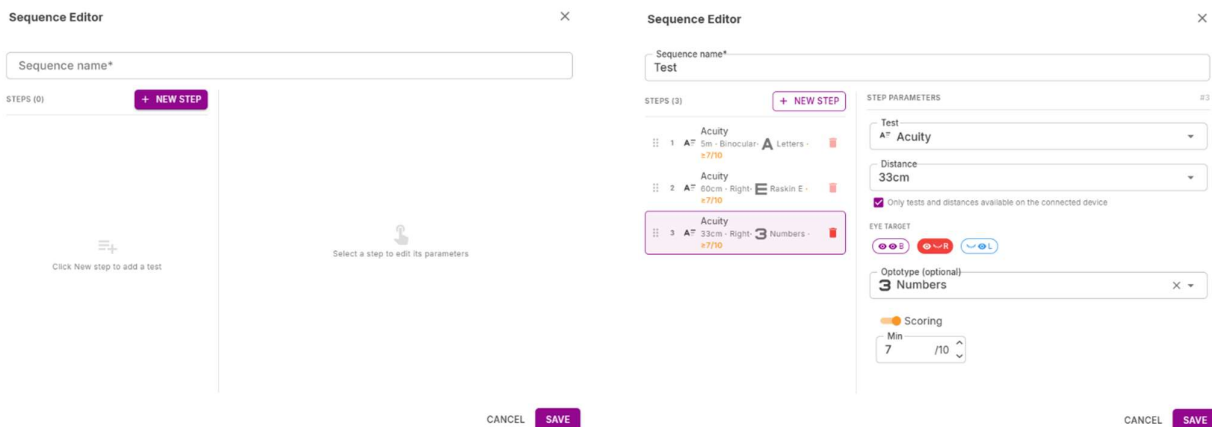
Examination configurations allow you to define:

- The unit for testing distances, using either the metric (m/cm) or imperial (ft/in) system.
- The unit of visual acuity results: LogMAR, MAR, Tenths, Tenths x10, Snellen 20ft, or 6m.
- Your own correction types (in addition to the default ones) using the input field and the "+" button. These custom corrections then appear in the dropdown list during exams and are recorded in the patient's report.

Sequences



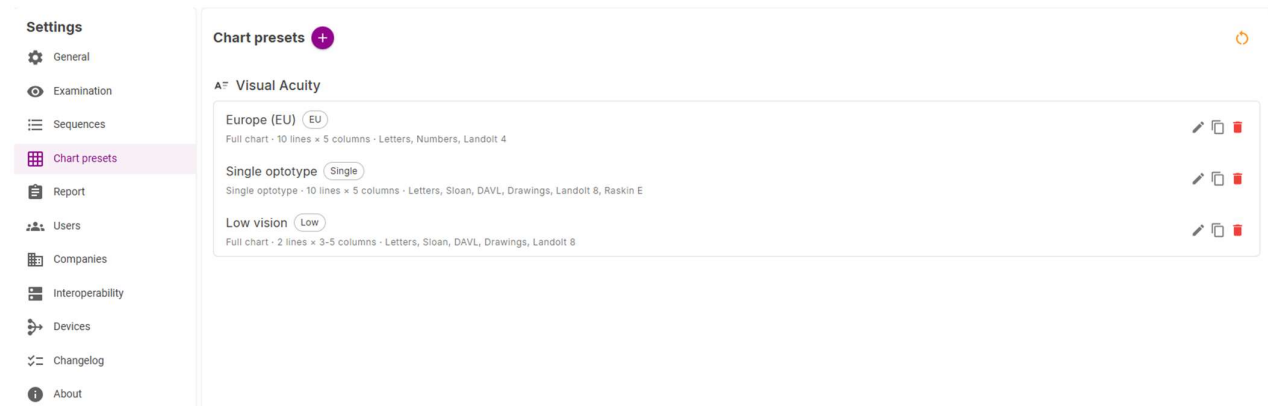
From this section, you can access all previously saved sequences in the software, modify or delete them, and preview the tests included in each sequence when selecting a particular sequence from the list. The Reset sequences button deletes all existing sequences and replaces them with the default sequences for the selected country.



To create a new sequence:

- Click the  button.
- Enter a name for the new sequence in the **Sequence name** field.
- Click + NEW STEP to add a test to the sequence.
- Select the test to be performed, then configure its parameters in the **STEP PARAMETERS** panel. Depending on the selected test, define the testing distance, the eye(s) to be tested, the optotype, and the scoring parameters.
- Repeat this process to add additional tests to the sequence.
- To change the order of the tests, drag and drop a step to the desired position in the sequence.
- To remove a test from the sequence, click the **Delete** icon next to the corresponding step.
- Click SAVE to save the sequence, or CANCEL to exit without saving.

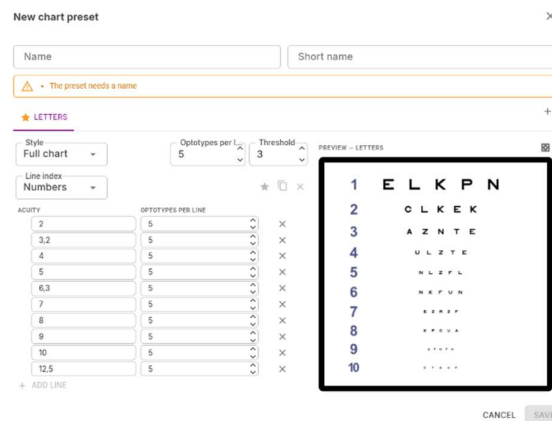
Chart presets



The Chart presets menu allows the user to create and manage visual acuity test charts.

Existing presets can be edited, duplicated or deleted. Click the + button to create a new preset.

Click the Reset icon in the upper-right corner of the Chart presets screen. Select the required country, then click RESET. The existing presets are replaced with the default presets for the selected country.



Creating a new test chart

- Click the + button.
- Enter a Name and a Short name for the new preset.

Managing optotype types

- Several optotype types can be included in the same test chart preset. Click the + button to add an available optotype type, such as Numbers, Sloan, DAVL, Drawings, Landolt 4, Landolt 8 or Raskin E. Each added type is displayed in a separate tab and can be configured individually.

For the selected optotype type:

- o Click the ★ Set as default icon to set it as the default optotype type for the preset. The default type is identified by an orange star.
- o Click the Duplicate icon to copy the current configuration to another optotype type or to All families.
- o Click the × icon to remove the selected optotype type from the preset.

Configuring the test chart



NOTE: Acuity values must be entered in strictly increasing order. If this condition is not met, a warning is displayed and the preset cannot be saved until the values are corrected.

NOTE: The software checks whether the configured optotypes can be correctly displayed within the available field. A warning is displayed if the configuration does not comply with the applicable **ISO 8596** display constraints or if optotypes may be clipped. Adjust the acuity value or the number of optotypes as required.

- Select the Style:
 - Full chart: displays all configured acuity lines on the same test chart.
 - Junior (paged): divides the test chart into several pages.
 - Single optotype: displays one optotype at a time.
- Select the Line index (Numbers or Dots) used to identify the acuity lines.
- Set Optotypes per line to define the number of optotypes displayed on each line.
- Set the Threshold to define the number of correctly identified optotypes required to validate an acuity line.
- In the ACUITY section, enter the acuity value for each line. The number of optotypes can be adjusted individually for each line.
- Click ADD LINE to add an acuity line or × next to a line to remove it.

Junior (paged) style



NOTE: If no page break is defined, the software displays the warning “**Junior style needs at least one page break**” and the preset cannot be saved.

- When Junior (paged) is selected, a PAGE BREAK option is displayed for each acuity line.
- Select PAGE BREAK after the required line to define where the current page ends and the next page begins. At least one page break must be defined when using this style.
- Use the ‹ and › buttons above the preview to navigate between pages.

Previewing the test chart

- The PREVIEW area displays the test chart according to the selected configuration and is automatically updated when the parameters are changed.
- Click the New draw icon to randomly generate a new arrangement of the optotypes while keeping the current test chart configuration.
- Once the configuration is complete, click SAVE to save the preset or CANCEL to exit without saving.

- Settings
 - General
 - Examination
 - Sequences
 - Chart presets
 - Report**
 - Users
 - Companies
 - Interoperability
 - Devices
 - Changelog
 - About

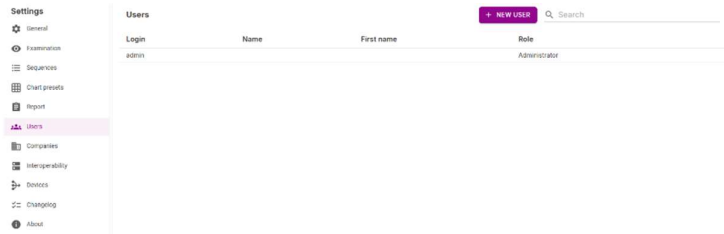
[illegible]

October 2026

Users



CAUTION: To ensure the protection of patient data, it is strongly recommended not to disable secure authentication access control to the VisioWin® software.



New user

Provider*
Database

Username* Role*
Technician

First name Name

Secret question* Answer*

Password* Confirm password*

New user

Provider*
LDAP

Username*

Role*
Technician

First name Name

The Users menu displays the list of registered users and allows new users to be added using the Database or LDAP provider.

Adding a user from the database

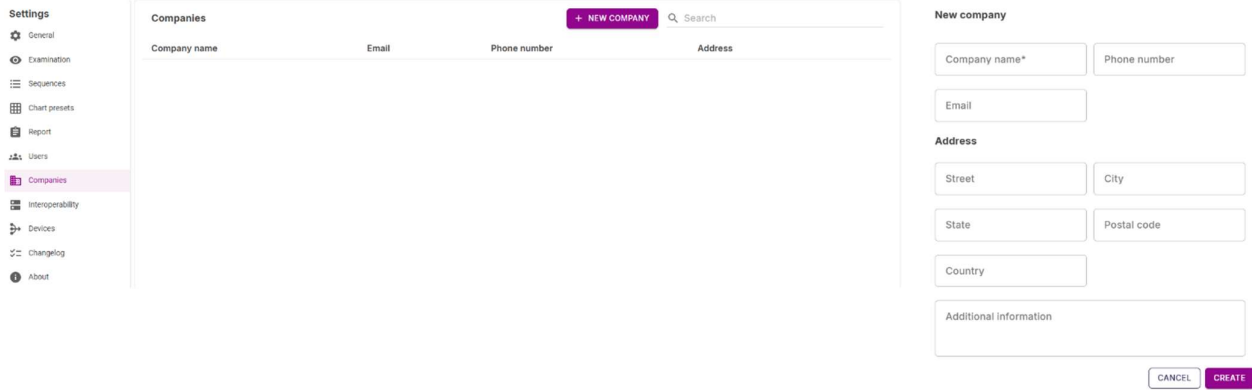
- Select Database as the Provider, then:
- Enter a Username.
- Select the appropriate Role.
- Enter the user's First name and Last name.
- Select a Secret question and enter the corresponding Answer.
- Enter and confirm the Password.
- Click CREATE to create the user, or CANCEL to exit without creating the user.

Adding a user from LDAP

LDAP (Lightweight Directory Access Protocol) allows VisioWin® to retrieve user information from a centralized directory and use the organization's existing authentication system.

- Select LDAP as the Provider, then:
- Enter the user's Username and click FIND to search for the user in the LDAP directory.
- If the user is found, the available user information is retrieved.
- Select the appropriate Role.
- Check or complete the user information, if required.
- Click CREATE to add the user to VisioWin®, or CANCEL to exit without creating the user.

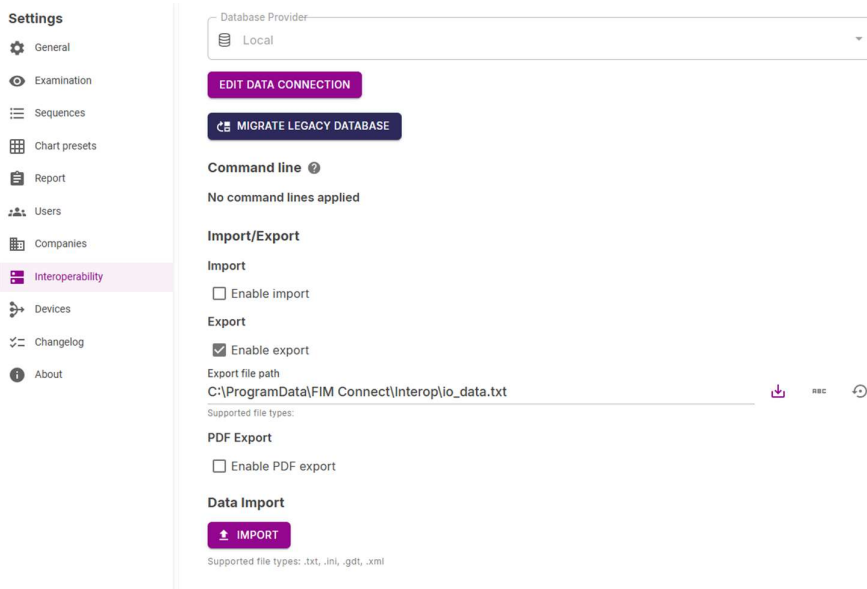
Companies



The 'Companies' settings page features a sidebar with navigation options: Settings (General, Examination, Sequences, Chart presets, Report, Users, Companies, Interoperability, Devices, Changelog, About). The main area displays a table with columns: Company name, Email, Phone number, and Address. A '+ NEW COMPANY' button and a search bar are at the top right of the table. To the right of the table is the 'New company' form, which includes input fields for Company name*, Phone number, Email, Address (Street, City, State, Postal code, Country), and Additional information. 'CANCEL' and 'CREATE' buttons are located at the bottom right of the form.

The company can be defined as that of the patient or the examiner, in which case the logo will be included in the examination report.

Interoperability



The 'Interoperability' settings page includes a sidebar with navigation options: Settings (General, Examination, Sequences, Chart presets, Report, Users, Companies, Interoperability, Devices, Changelog, About). The main area displays the 'Interoperability' settings. At the top, there is a 'Database Provider' dropdown menu with options: Local, Remote, and No database. Below this are buttons for 'EDIT DATA CONNECTION' and 'MIGRATE LEGACY DATABASE'. The 'Command line' section shows 'No command lines applied'. The 'Import/Export' section has checkboxes for 'Enable import' and 'Enable export'. The 'Export file path' is set to 'C:\ProgramData\FIM Connect\Interp\io_data.txt'. The 'Supported file types' are listed as '.txt, .ini, .gdt, .xml'. The 'PDF Export' section has a checkbox for 'Enable PDF export'. The 'Data Import' section has an 'IMPORT' button and lists supported file types: '.txt, .ini, .gdt, .xml'.

Select the Database Provider: Local (database stored locally), Remote (external PostgreSQL database), or No database.

VisioWin® automatically applies the corresponding settings to facilitate data exchange.

Available options:

- Enable import: allows patient data to be imported from the EMR.
- Enable export: allows patient data and examination results to be exported to the EMR.
- Enable PDF export: allows examination reports to be exported in PDF format.

Devices

Settings

- General
- Examination
- Sequences
- Chart presets
- Report
- Users
- Companies
- Interoperability
- Devices**
- Changelog
- About

Devices

LAN WHITELIST

Device Type	Serial Number	Configuration	Slide Bank	Firmware	Connection	Status
Visiolite Flex	VLFX260034	-	-	1.0.0	Wired	Connected

Displays the list of all currently connected devices along with their associated information (model, serial number, device version, etc.).

Click the LAN WHITELIST button to add devices connected via a LAN (Ethernet) RJ45 cable.

Changelog

Displays all of the elements modified or added during an update.

About

Settings

- General
- Examination
- Sequences
- Chart presets
- Report
- Users
- Companies
- Interoperability
- Devices**
- Changelog
- About**

VisioWin

Application Name: VisioWin

Version 2.1.0.0

Build: 7c8cce4

Target Framework: .NETCoreApp,Version=v10.0

Description: Vision screening software

Company: FIM Medical

Author: FIM Medical

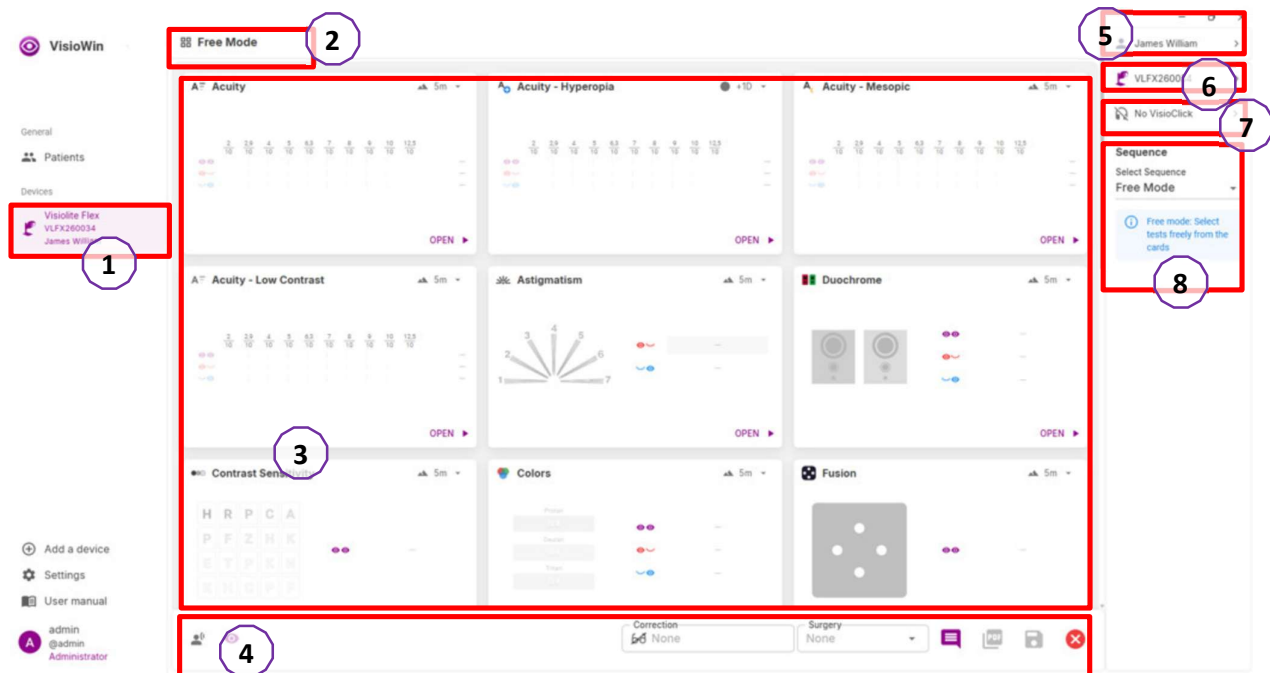
Copyright: © 2025 FIM Medical. All rights reserved.

Support: support@fim-medical.com

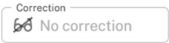


Displays software and regulatory information, including the application version, company details, support contact, and CE/medical device marking.

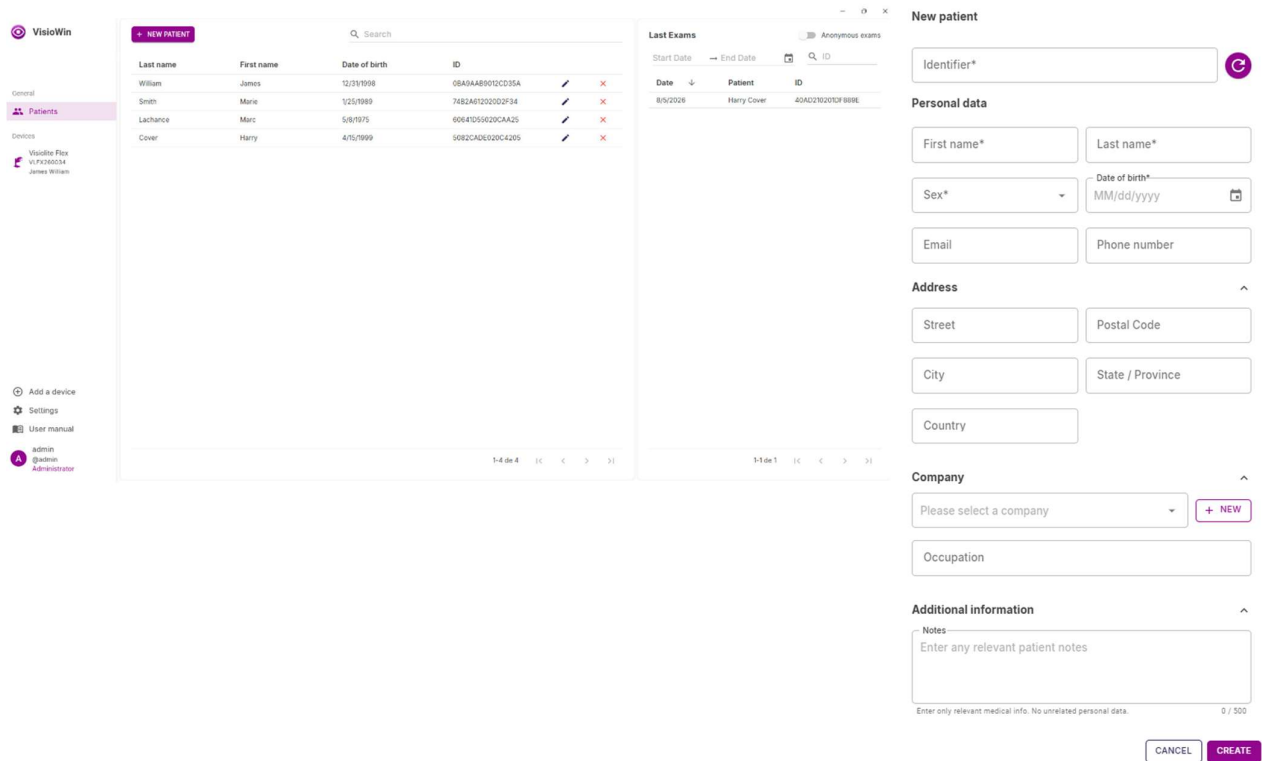
Examination window



1. **Navigation menu:** Provides access to the connected vision screener and the examination window.
2. **Examination name:** Displays 'Free Mode' when the operator selects tests individually instead of running a predefined sequence, or the name of the selected test sequence.
3. **Examination window:** Displays and provides access to the available tests.
4. **Toolbar:** Provides access to test settings, comments, patient clinical information, report generation, and saving the current test.
5. **Patient profile:** Creates a patient profile and/or displays patient information.
6. **Visiolite® information:** Displays the status, configuration and technical information of the connected Visiolite® Flex, including the device and hardware versions, system performance, and available viewing distances. It also allows the user to: set the standby delay or check whether the device is up to date and install an update when available.
7. **VisioClick® information:** Displays the status, language configuration and technical information of the connected VisioClick®.
8. **Sequence settings menu:** Allows selection, launch, and monitoring of a test sequence.

Button/Indicator	Meaning	Button/Indicator	Meaning
	Activates or deactivates detection of the patient's forehead position. The indicator turns green when the forehead is detected and red when it is not.		Allows the operator to enter free-text notes related to the current examination.
	Turns on if the Multi Voice Instruction is activated. Allows access to Multi Voice Instruction settings, such as language selection (French, Dutch, English, German, Italian, Polish, Portuguese, Spanish) and volume.		Generates a PDF report of the completed examination.
	Indicates whether the patient is wearing corrective lenses and, if so, specifies the type.		Saves the current examination.
	Indicates whether the patient has undergone a surgical procedure and, if so, specifies the type.		Clears the current examination and resets it to start over.
	Activates or deactivates Eye Tracking (Premium version).		

Patient profile management (for patients not managed via a third-party/EHR interface)



Last name	First name	Date of birth	ID
William	James	12/31/1998	08A8AAB910CD35A
Smith	Marie	1/25/1989	7482A6720202F34
Lachance	Marc	5/8/1975	6064D55620CA425
Cover	Harry	4/15/1999	5082CA26520C4205

New patient

Identifier*

Personal data

First name* Last name*

Sex* Date of birth* MM/dd/yyyy

Email Phone number

Address

Street Postal Code

City State / Province

Country

Company

Please select a company + NEW

Occupation

Additional information

Notes

Enter any relevant patient notes

Enter only relevant medical info. No unrelated personal data. 0 / 500

CANCEL CREATE

This page allows you to view the list of all registered patients, create a new patient profile, or select an existing patient profile to start an examination.

If no patient is selected, the examination will be carried out anonymously.

From the side menu, click on the patient icon  to access the patient profile viewing interface.

Button	Meaning
	Filter the database to select an existing profile
	Create a new patient
	Edit the profile of the selected patient
	Delete the profile of the selected patient

When you select a patient, you can view that patient's exam history in the right-hand window. This window can also be used to view previous examinations in anonymous mode (once this option is enabled) and to filter results according to various criteria.

To create a new patient profile, click the corresponding button in the table above and fill in all the required fields.

13. Conducting an exam



WARNING: Follow the cleaning directions for the device and the removable forehead rest mentioned in the Cleaning section to avoid risk of cross-contamination.

Precautions for use

The equipment works on the basis of binocular fusion. The operator must ensure that the patient has sufficient fusion to carry out the examination.

Before any examination, the patient should be asked if he or she usually wears optical correction.

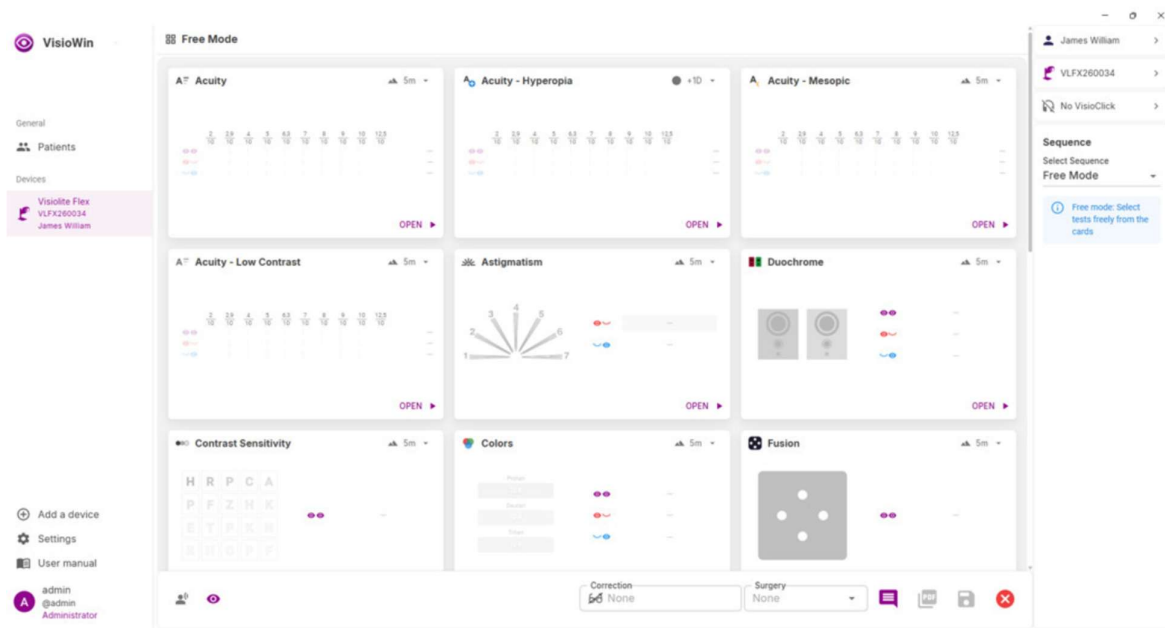
For photosensitive patients, the light level can be reduced at any time during the examination.

The examination should be carried out in an appropriate environment, ensuring that the patient is not disturbed by a light source external to the device.

In the case of a glare test, the operator must inform the patient of the test procedure and ensure that there is no persistent discomfort at the end of the test.

Once an examination is completed, the operator must clean the device, especially the parts in contact with the patient.

Selecting a test

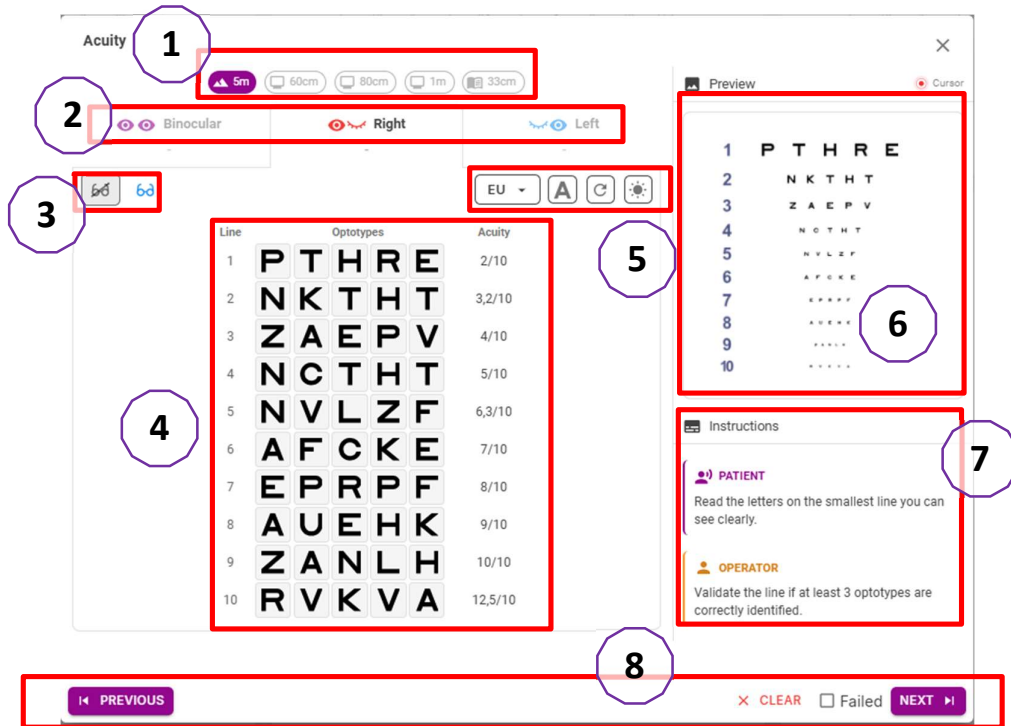


Visual tests are available on the Examination window and are represented by thumbnails.

Each thumbnail corresponds to a visual ability for which different test conditions can be modified: optotype model, vision, distance, or lighting conditions.

To launch a specific test, click the OPEN button in the bottom-right corner of the thumbnail.

Test interface



Although each test serves a different purpose, they all share a similar interface, presented as follows:

1. Choose the distance to be tested:

	Far Vision		Near Vision
	Intermediate Vision		

2. Choose the eye to be tested

	Binocular		Left eye
	Right eye		

3. Choose whether the patient is wearing corrective lenses during the test or not. (To be indicated first in the Toolbar of the Examination window before launching a test).

	The patient is not wearing corrective lenses		The patient is wearing corrective lenses
---	--	---	--

4. View of the optotypes and the area where you can click on the optotypes seen by the patient.

5. This section is divided into 4 parameters:

Pack selection:

Choose the optotype pack to be applied to the test. The available packs are grouped into three categories:

- Regional standards (e.g., Europe, United Kingdom, Germany, United States): Automatically selected according to the computer's system configuration. The regional standard can be changed in Settings > Chart presets.
- Single optotype: Displays one optotype at a time instead of a full line, particularly suitable for patients affected by visual crowding.
- Low vision: Uses larger optotypes suitable for patients with significantly reduced visual acuity.

Optotype selection:

- Choose the optotypes to be used during the test.

	Letters or SLOAN		Landolt 8 positions
	Numbers		FIM symbols
	Raskin E		DAVL
	Landolt 4 positions		

Start over:

Restarts the test from the beginning. This reset generates random optotypes to prevent memorization and ensure more accurate results.

Photopic:

	High photopic: Normal light output		Low photopic: Halves the light output of the Visiolite® FLEX.
---	------------------------------------	---	---

The change from high to low photopic or vice-versa will automatically generate random optotypes to prevent memorization and ensure more accurate results.

- Shows a preview of how the test will appear on the Visiolite® FLEX screen and what the patient actually sees on the device.
- Displays the instructions given to the patient for performing the test, as well as the instructions for the operator on how to proceed.
- This section is divided into three parts:

Navigation:

The Previous and Next buttons allow you to scroll through the tests within the thumbnail or the sequence.

Clear:

Deletes the results recorded during the test.

Failed:

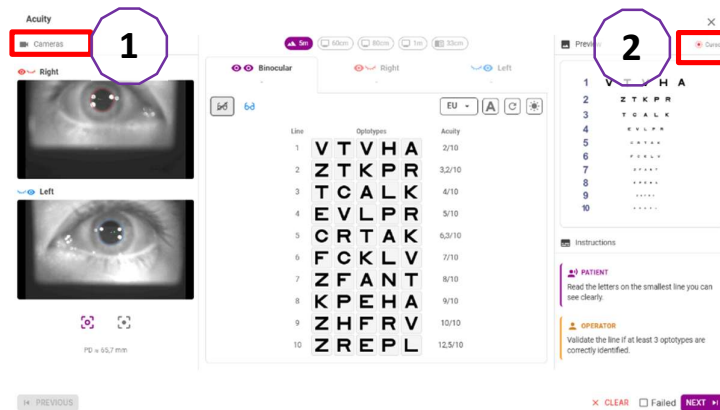


NOTE: A justification comment is required for any failed test. It must be entered in the comment field located in the toolbar of the Examination window.

Check this box if the patient cannot see anything or did not understand the instructions.

Patient monitoring tools:

Patient monitoring tools allow the operator to track the patient's eye position and direct their attention during the examination.

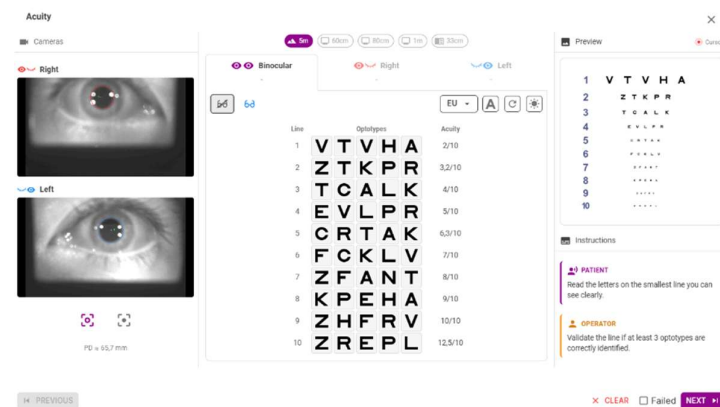


Eye-tracking:

The Visiolite® Flex integrates two infrared cameras for eye tracking. The images are not recorded; they are used only for real-time display.



Enable Eye Tracking from the toolbar on the examination page to access this feature.

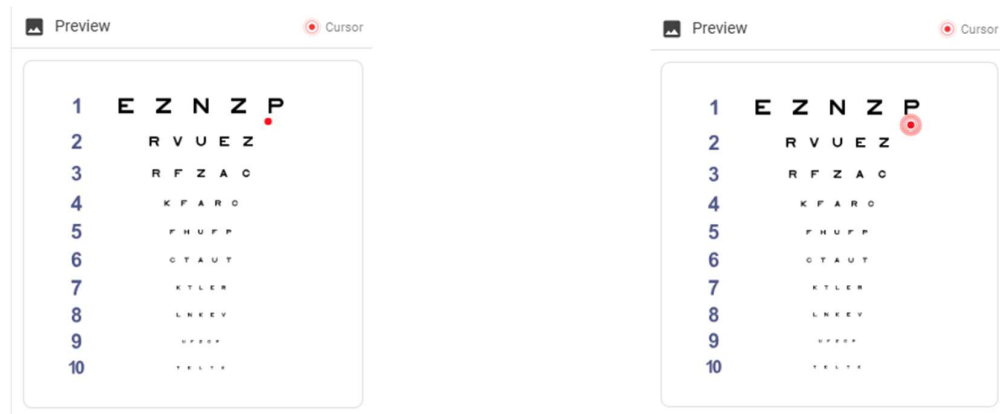


This left panel displays the real-time eye-tracking view of the patient's right and left eyes during the test, allowing the operator to visually monitor eye position and fixation.

The following controls allow the Eye Tracking system to be quickly calibrated or zeroed and provide the patient's pupillary distance (PD).

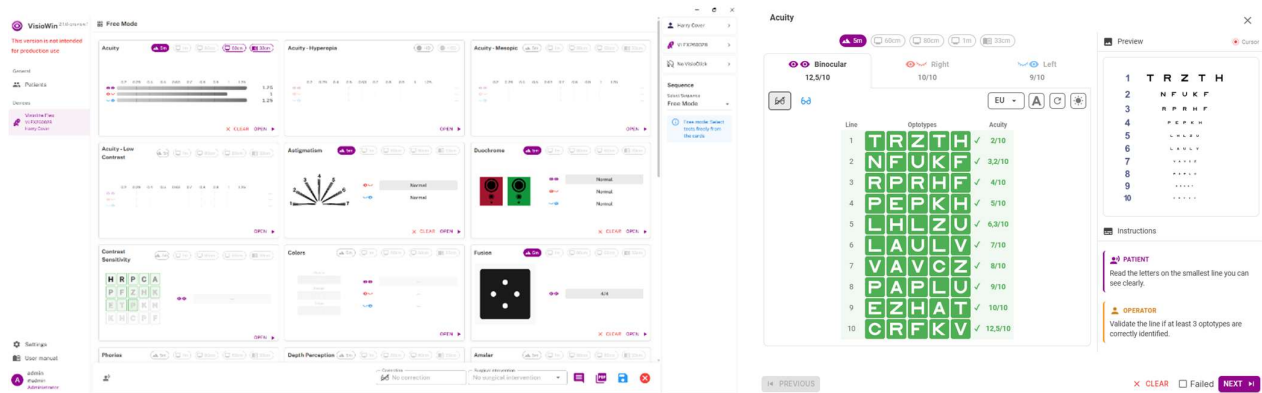
	Performs a quick calibration of the Eye Tracking system to the patient's gaze.		Sets the patient's current gaze position as the reference position.
---	---	---	--

Cursor



The cursor is used to direct the patient's attention to a specific optotype. To use it, simply place your mouse over the desired line or optotype in the Preview section — the patient will see a red dot appear on the device. You can draw further attention to it by right-clicking.

Manual Mode



- Create or assign a patient.
- Indicate whether the patient is wearing corrective lenses for the examination or has undergone a surgical procedure.
- Select the test you want to start and click OPEN.
- Select the distances, eye(s) to be tested, optotypes, and other test settings, as described previously.
- Follow the instructions provided for each test to ensure it is performed correctly.
- Click NEXT or CLOSE, if applicable, to navigate through the tests.
- Repeat the process for any other tests you wish to perform.
- Once the examination is complete, fill in the comment section if necessary.
- Click the SAVE button.
- You can then generate the examination report by clicking the PDF button.

Thumbnail presentation



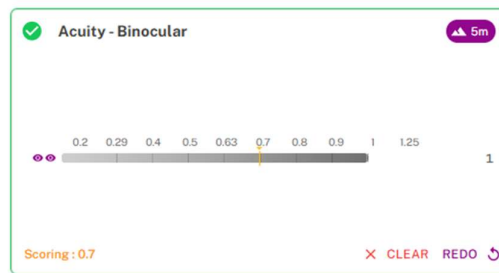
During and after the examination, the result is reported in the thumbnail of the corresponding test.

At the top-right corner of the thumbnail, the icons indicate the distance used during the test.

The distance(s) used are highlighted.

If several distances were used, you can switch between far, intermediate, and near vision by clicking the corresponding distance icon.

The selected icon will then be fully highlighted in purple.



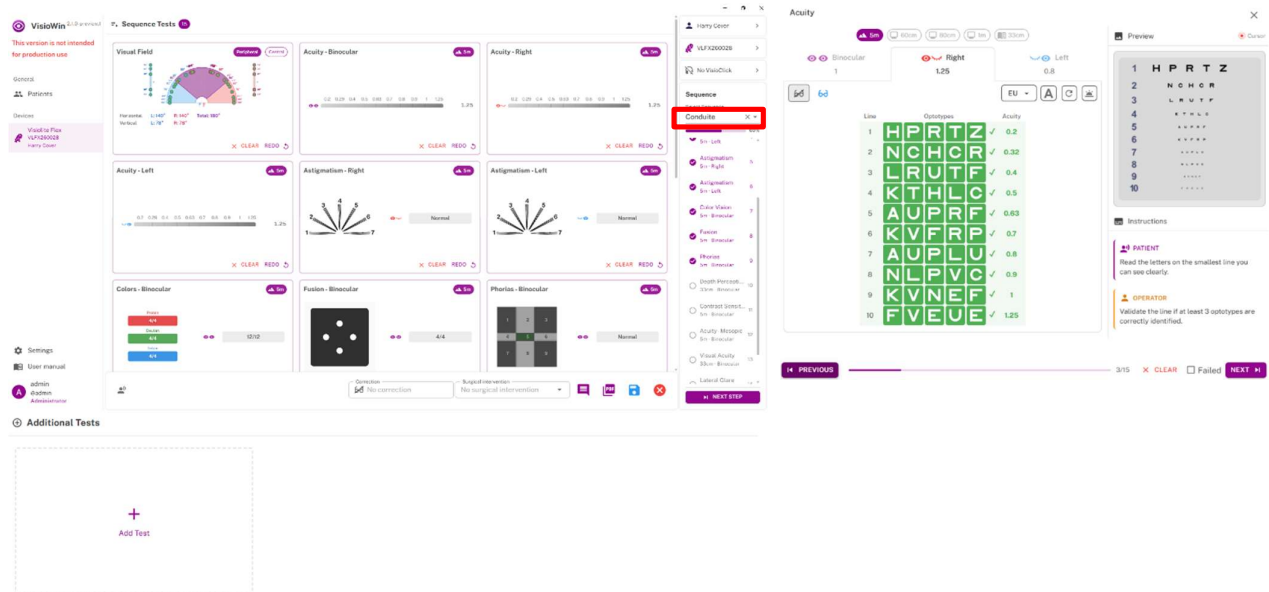
Visualization of scoring

If a scoring parameter is enabled, it is shown in the bottom-left corner of the thumbnail. Scored results are marked with a yellow indicator for easier identification.

Test Sequences



NOTE: Only the tests included in the selected sequence will appear in the Examination window.



- Create or assign a patient.
- Indicate whether the patient is wearing corrective lenses for the examination or has undergone a surgical procedure.
- Select the sequence you wish to use for the examination from the drop-down menu highlighted in red. The tests included in the sequence will appear below in chronological order.
- Click the START button.
- Follow the instructions provided for each test in order to perform the test correctly.
- Use the NEXT STEP button or the PREVIOUS button to navigate through the tests in the sequence.
- You can monitor the progress of the examination using the progress bar located below the red box. A progress bar also appears in the bottom section of each test.
- You can restart an individual test, if necessary, by clicking the REDO button.
- You can add a new test to the sequence at any time by clicking the ADD TEST button in the additional tests section, located at the bottom of the examination window, and selecting the desired test(s) along with the required parameters.
- Once the examination is complete, fill in the comment section if necessary.
- Click the SAVE button.
- You can then generate the examination report by clicking the PDF button.

Automated mode with VisioClick®



WARNING: For hygiene and biocompatibility reasons, it is essential to use FIM Medical single-use hygienic ear covers with the VisioClick® headphones.

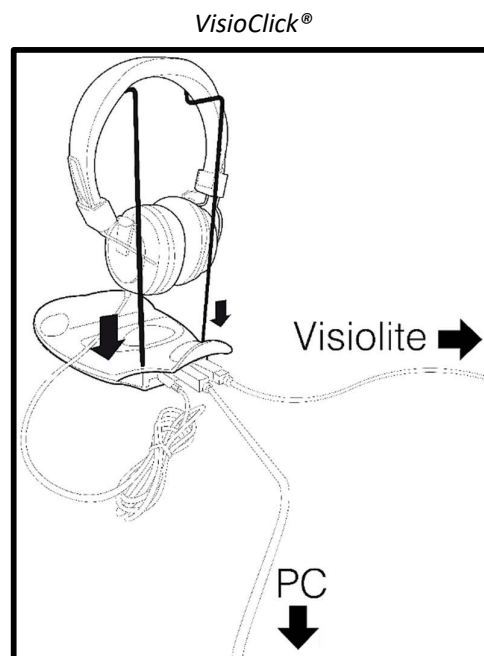
WARNING: Single-use ear covers must be used for every examination and replaced between each patient.



NOTE: Avoid using the VisioClick® in a noisy environment that prevents proper understanding of the spoken instructions given through the audio headset.

NOTE: Glare sensitivity testing cannot be performed with VisioClick®.

NOTE: Although the VisioClick® device provides the patient with a certain level of autonomy, a healthcare professional must always remain in the immediate vicinity to ensure that the examination runs smoothly.

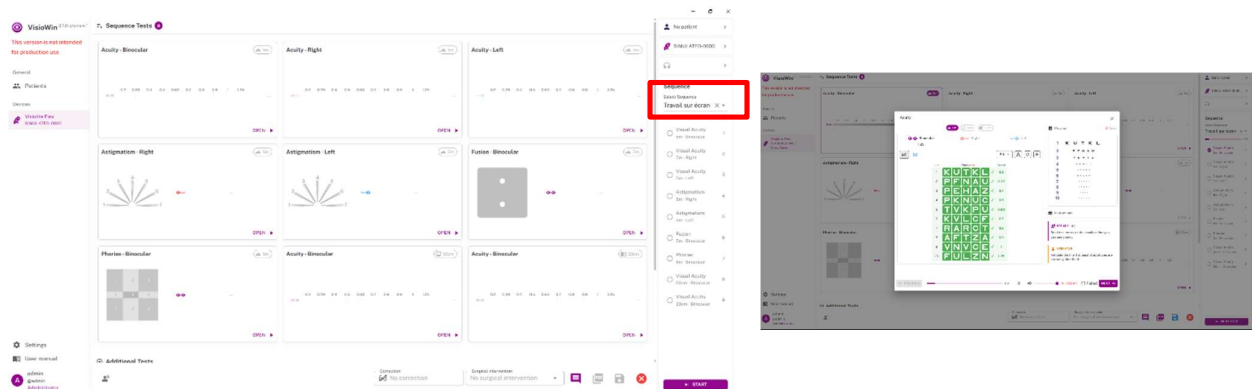


- Position the metal headset holder in the two holes of the VisioClick®.
- **Connect the Visiolite® FLEX USB cable to the VisioClick®:** Type A connector to the VisioClick®, Type B connector to the Visiolite® FLEX.
- **Connect the VisioClick® USB cable to the PC:** Type B connector to the VisioClick®, Type A connector to the PC.
- Connect the headset jack plug to the VisioClick®.



Once all connections have been made correctly, the VisioClick® and the headset must appear as detected in the status bar of the VisioWin® software.

Launching an examination in automated mode with VisioClick®



- Create or assign a patient.
- Indicate whether the patient is wearing corrective lenses for the examination or has undergone a surgical procedure.
- Select the sequence you wish to use for the examination from the drop-down menu highlighted in red. The tests included in the sequence will appear below in chronological order.
- Click the START button.
- You can monitor the progress of the examination using the progress bar located below the red box. A progress bar also appears in the bottom section of each test.
- You can restart an individual test manually, if necessary, by clicking the REDO button.
- You can add a new test to the automated sequence at any time by clicking the ADD TEST button in the additional tests section, located at the bottom of the examination window, and selecting the desired test(s) along with the required parameters.
- Once the examination is complete, fill in the comment section if necessary.
- Click the SAVE button.
- You can then generate the examination report by clicking the PDF button.

14. Description of tests

Visual acuity tests

Purpose and presentation of the test:

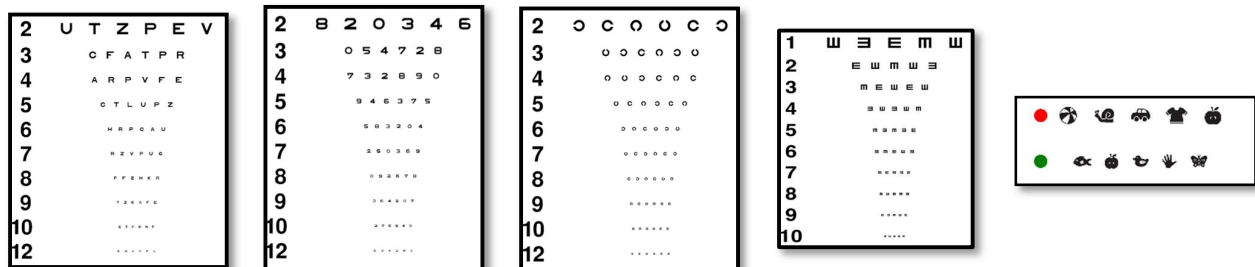
The visual acuity test is the starting point for any eye examination. It ensures that a patient has the correct correction and assesses his or her ability to decipher everyday information. During an examination, the aim is generally to achieve visual acuity of 10/10 or even 12/10. This will enable the subject to decipher everyday information such as the name of a street on a sign or articles in a newspaper. The test is carried out in a variety of ways: monocularly, binocularly, at a distance, at an intermediate distance, at close range, with compensation, without compensation, in a photopic or mesopic environment. These different acuities will tell us about a patient's visual abilities.

These tests include the following within Visiolite® FLEX:

- Distance visual acuity
- Intermediate visual acuity
- Near visual acuity
- It is also possible to blur a patient's eye by one diopter in order to assess a tendency towards hyperopia.
- Visual acuity in a mesopic environment to test the patient's vision at twilight
- Low vision to assess a subject's aptitude for driving, testing monocular visual acuity at 0.5/10 and 1/10.

The various tests on offer assess two types of visual acuity: recognition acuity, also known as morphoscopic acuity, and resolution acuity. It may be useful to test both in order to assess certain specific problems. The optotypes used are as follows:

- Letters
- Numbers
- Landolt rings
- Raskin E
- DAVL Symbols



Execution of the test:

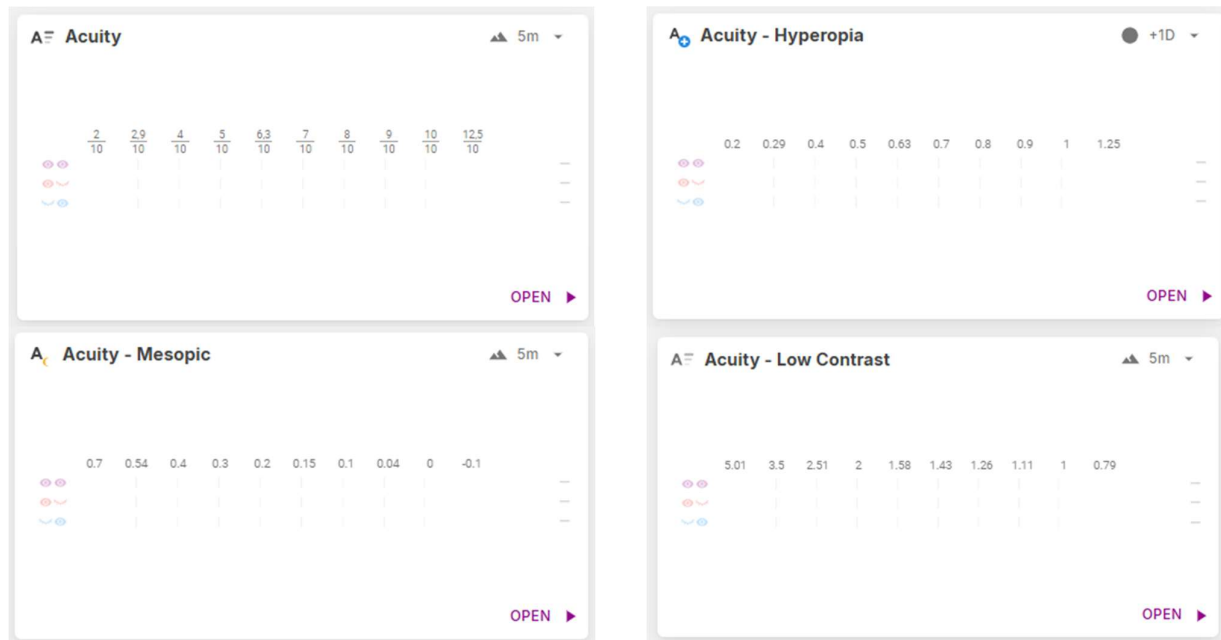
It is a good idea to start with a gross visual acuity assessment (a basic evaluation of visual function, without precise optotypes) on the weaker eye, in order to avoid any memory effect. This can be followed by the acuity of the other eye and then the binocular acuity.

This test should first be performed for distance vision, then for near vision and possibly for intermediate vision.

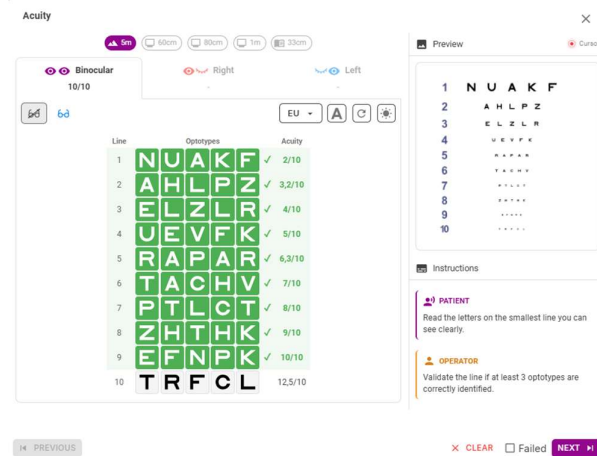
You can then use the same procedure to measure the patient's compensated acuity.

The visual acuity tests are divided into as many thumbnails as there are distance (near, intermediate, far) and lighting (photopic/mesopic) situations to be tested.

Description of the VisioWin® interface



Visual acuity tests are divided into four thumbnails according to the test configuration: Normal, Photopic, Mesopic, and Hyperopia.



In the response entry window, click on each optotype perceived or on the line number to the left of the line or acuity number to the right of the line to validate the acuity if the minimum validation threshold of optotypes has been successfully recognized by the patient.

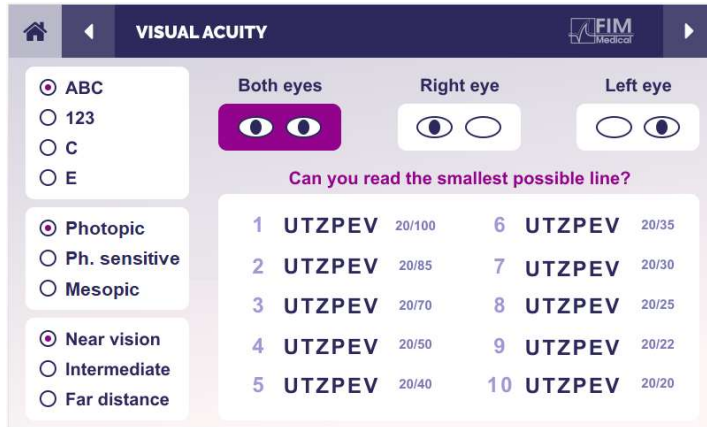
It is also possible to validate or invalidate the perception of an optotype with a click or a double-click on the optotype respectively.

The perceived optotype is then colored green, and the unrecognized one stays white.

It is not necessary to validate every optotype individually: validating the optotype with the lowest acuity automatically validates all the easier ones before it.

The unit of the result and validation threshold are to be defined in the examination section of VisioWin® settings.

Description of the Remote-Control interface



The remote-control interface allows you to view the test conditions currently being performed:

- Type of optotype displayed
- Display brightness level
- Viewing distance
- Eye being tested
- Question to ask
- Optotypes displayed

Read the question aloud and record the patient's response on the answer form.

Instructions to be given to the patient

Depending on the selected optotype type, ask the following question:

- Letters: "Read the letters on the smallest line you can see clearly."

Contrast sensitivity test

Purpose and presentation of the test

This test reveals a drop in contrast sensitivity, which may reflect damage to the retina caused by diseases such as cataracts, chronic glaucoma or diabetic retinopathy.

Reduced contrast sensitivity can also occur after eye repair surgery.



The test is based on the MARS contrast sensitivity test. The test offers 20 different levels of contrast which decrease according to the distribution below. Contrast sensitivity is expressed as a percentage, with 100% being the highest contrast and 1.2% being the lowest. To ensure that differences in visual acuity between subjects do not bias the result, the optotypes are presented at a fixed acuity level of 2/10.

The tables below show the different contrasts, expressed as a percentage, used in the test.

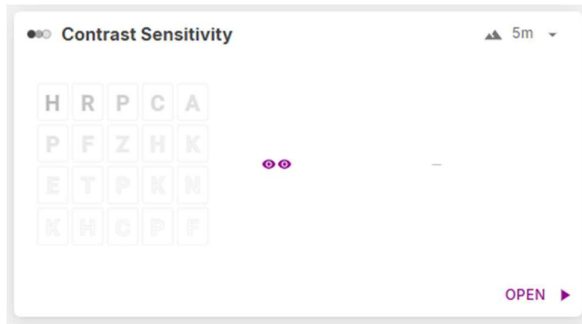
1	H	R	P	C	A
2	P	F	Z	H	K
3	E	T	P	K	N
4	K	H	C	P	F

1	100	80	63	50	40
2	32	25	20	16	12.5
3	10	8	6.3	5	4
4	3.2	2.5	2	1.6	1.2

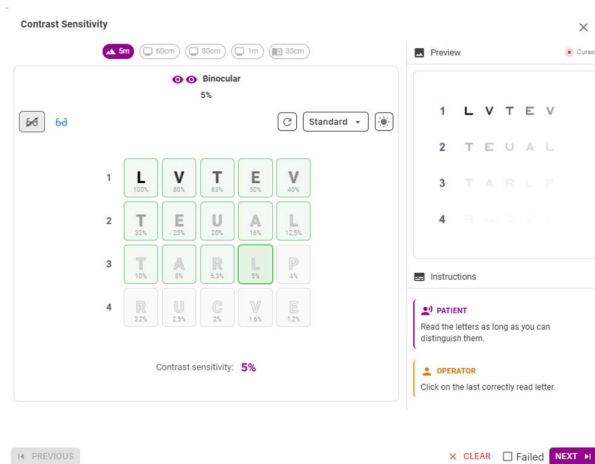
Execution of the test:

- This test is performed binocularly.
- This test is recommended for distance vision.
- This test must be carried out with the patient's compensation.
- This test is recommended in high photopic mode but can also be performed in low photopic mode.
- The patient must have a visual acuity of at least 2/10.

Description of the VisioWin® interface



The thumbnail shows the contrast gradient as seen by the patient and the exam result as a percentage.

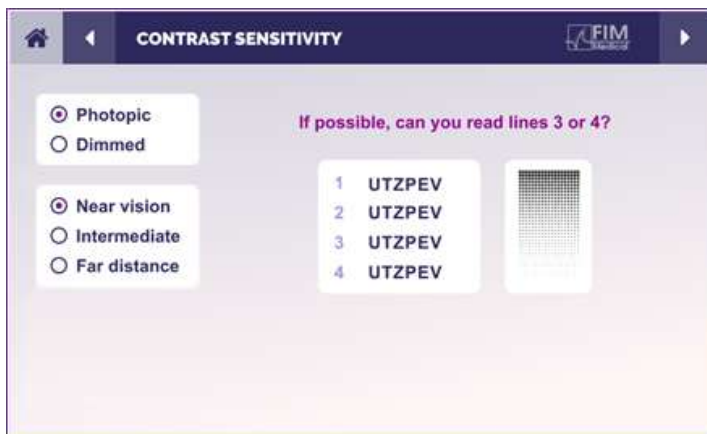


In the response entry window, click on the optotypes correctly recognized by the patient.

Contrast sensitivity is then gradually calculated as responses are received and transcribed into the test thumbnail in the background.

It is not necessary to validate all letters individually; validating the optotype with the lowest contrast will automatically validate all previous ones.

Description of the Remote-Control interface



The remote-control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Test displayed
- Question to ask

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Depending on the selected optotype type, ask the following question:

- Letters: "Read the letters as long as you can distinguish them."

Astigmatism test

Purpose and presentation of the test

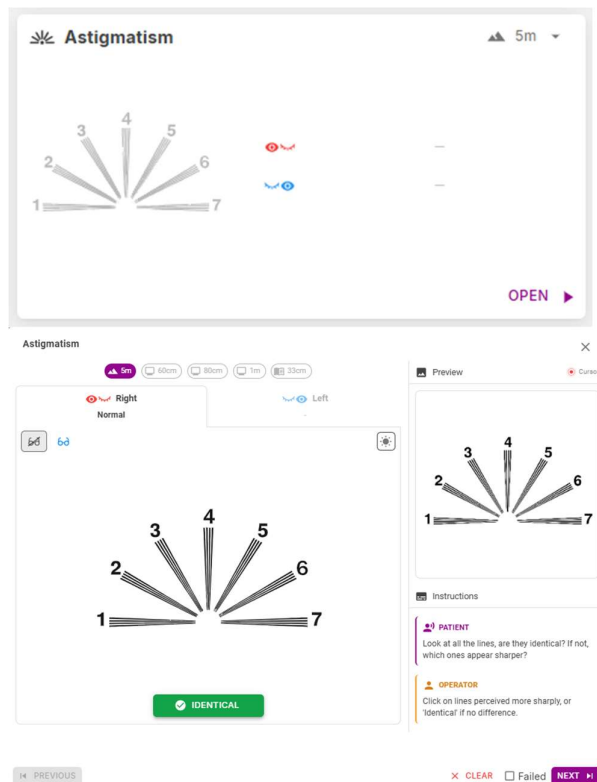
This test is used to detect an astigmatism defect in a patient. Astigmatism is caused by an incorrect relationship between the power of the eye and its length. The astigmatic person's vision will then be distorted in a particular direction. If the astigmatism is too great, the patient will have poor acuity at any distance. This type of defect can be compensated for with astigmatic lenses.

This test consists of seven meridians, each spaced 30° apart. Each axis is represented using three lines to increase the test's sensitivity. The numbers on the lines are presented at an acuity of 2/10.

Execution of the test:

- This test is performed monocularly.
- This test should preferably be performed at a distance in order to limit accommodation.
- The patient may or may not be wearing compensation depending on what you wish to test.
- This test is generally performed in a photopic environment.

Description of the VisioWin® interface



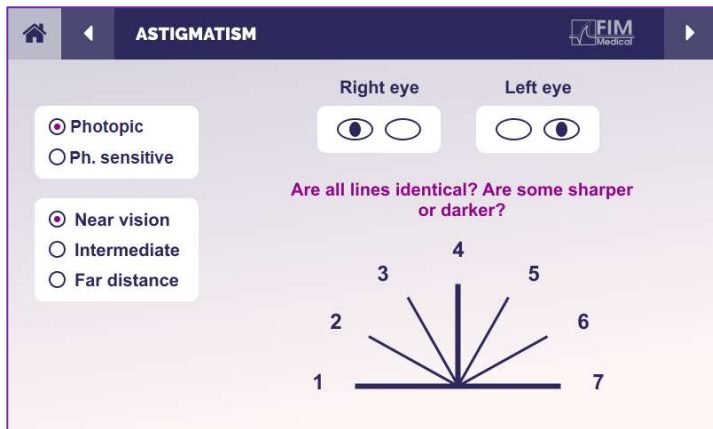
The thumbnail shows the meridian axes of each eye, with numbers for each axis.

In the response entry window, click on the line or lines perceived most clearly by the patient.

Click on Identical if the patient does not distinguish a difference.

The number of the line entered is then colored red if abnormal or green when identical.

Description of the Remote-Control interface



The remote-control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Eye being tested
- Question to ask
- Test displayed

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: "Look at all the lines, are they identical? If not, which ones appear sharper?"

Full visual field test

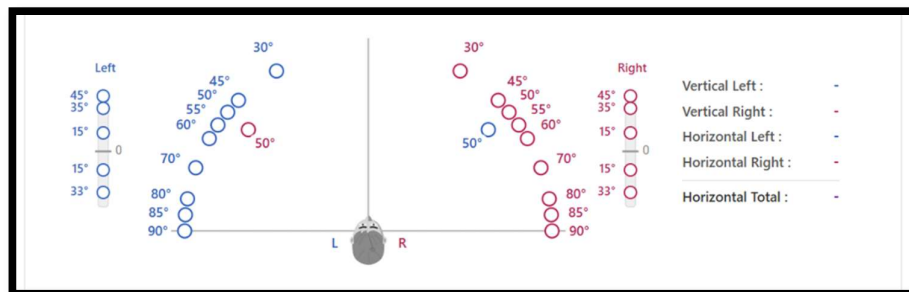
Purpose and presentation of the test

The visual field makes it possible to highlight various vision disorders. It is essential for diagnosing blind spots caused by scotomas, damage to the optic nerve, or issues within the cerebral cortex. The table below shows the extent of the visual field measurable by the Visiolite® FLEX. The values are not symmetrical, notably due to the shape of the nose. At binocular level, the horizontal fields add up, giving a common area for both eyes of 120°, surrounded by two crescents of monocular vision of 30° called half-moon fields. The total horizontal binocular field tested is therefore 180°.

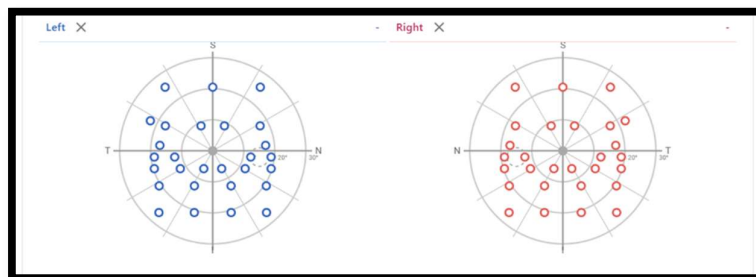
The visual field examination is based on two complementary tests: analysis of the central field and analysis of the peripheral field. The first tests the central 30° to 60° of vision, whereas the second tests the rest of the visual field. The peripheral field is evaluated using a procedure similar to a static Goldmann test, while the central field is assessed using an Esterman grid. Both tests can also be run together in a single examination called Advanced mode, which represents the patient's complete visual field.

Monocular	Monocular	Binocular	Binocular
Nasal	50°	Horizontal	180°
Temporal	90°	Vertical	90°
Superior	45°		
Inferior	45°		

Visual field extent tested by Visiolite® FLEX



The peripheral field is tested using 60 light stimuli



The central field is tested using 56 light stimuli

The peripheral field is tested using 15 diodes per eye (30 in total), distributed across multiple meridians of the visual field, in a manner similar to a static Goldmann perimetry test.

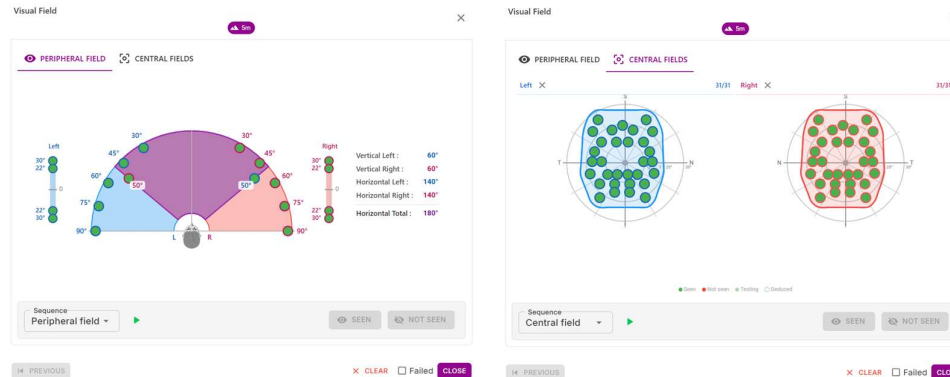
The central field will test the central 30° to 60° of vision using 28 diodes per eye. The stimuli are arranged in the manner of an Esterman grid, which gives more importance to lower vision and to the horizon line.

Perimetry is performed here in static mode, which means that the stimulus will be activated for a short instant during which the patient must be able to see it. The activation time of the light stimulus is 300 ms.

Execution of the test:

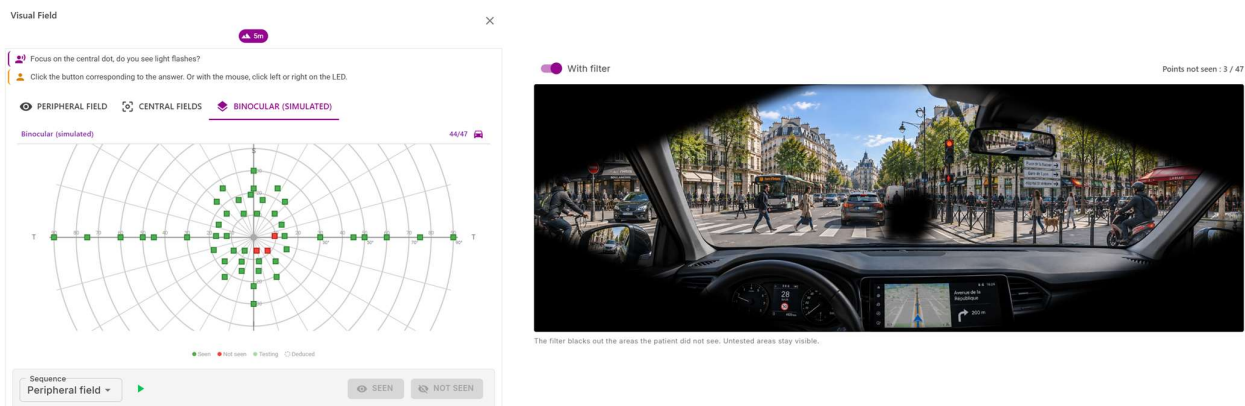
- This test is performed monocularly.
- The patient is wearing their correction.

Description of the VisioWin® interface



The visual field thumbnail is split into three tabs to test the peripheral field, the central field, or get a simulated binocular field:

- A first tab dedicated to the peripheral field presenting the extent of the peripheral field measured during the test: vertical and horizontal axis of each eye as well as the complete horizontal axis.
- A second tab dedicated to the central field with the number of diodes perceived for each eye according to the angular extent.
- A third tab presents the combined binocular result, obtained by summing the results of both eyes. The car icon displays a simulation of the resulting effect on the view from the driver's seat.



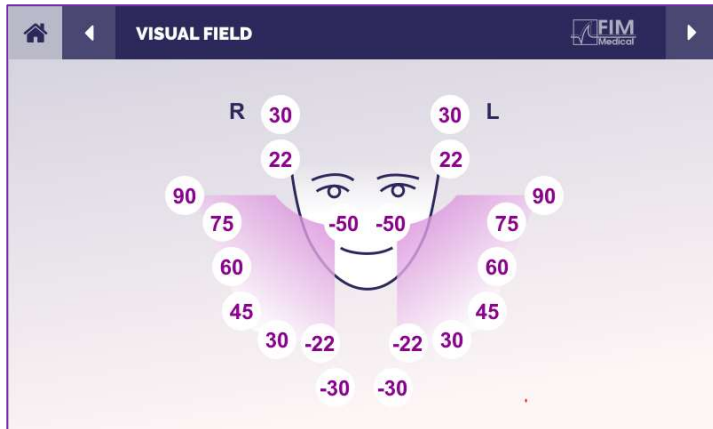
The test can be performed either manually by selectively clicking on the points to be tested or can follow a predefined display sequence, selected from the Sequence menu (e.g. Complete field), by clicking the play button.

Each time a point is selected, click the SEEN button (or left-click on the flashing light point) to confirm perception of the light stimulus, or click NOT SEEN to mark it as not perceived. The points will then turn green or red respectively.

It is also possible to reset a point by reselecting the concerned stimulus, to return to the previous point using PREVIOUS, or to restart the entire test by clicking CLEAR. The test can be marked as Failed if it cannot be completed, and CLOSE ends the test session.

When Eye Tracking is enabled, the operator can monitor the patient's gaze during the test and check that the patient is looking straight ahead while the light stimuli are presented.

Description of the Remote-Control interface



The remote-control interface allows you to view the different peripheral field diodes and the corresponding angles.

Press the different circles to light up the associated diode and note on the response form whether the patient perceived the light emitted by the diode.

The central field test is not available in the remote-controlled version.

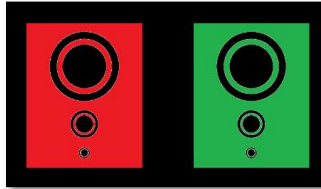
Instructions to be given to the patient

Ask the following question: "Look straight ahead and stare at the central point. On which side do you see the little light appearing?"

Duochrome test

Purpose and presentation of the test

Also known as the bichromatic test or the red-green test, this test is used to confirm a patient's hyperopia. It is based on the chromatic dispersion of the eye. As the eye is an optical system, it breaks down light like a prism. Green wavelengths are therefore deviated more than red ones. Depending on how easy it is to read against a red or green background, it is possible to determine the patient's ametropia. If the patient is hypermetropic, the green wavelengths will be closer to the retina, whereas if the patient is myopic, the red wavelengths will be closer to the retina. However, this test can be distorted by the patient's accommodation, which is why it is mainly used to detect hyperopia.

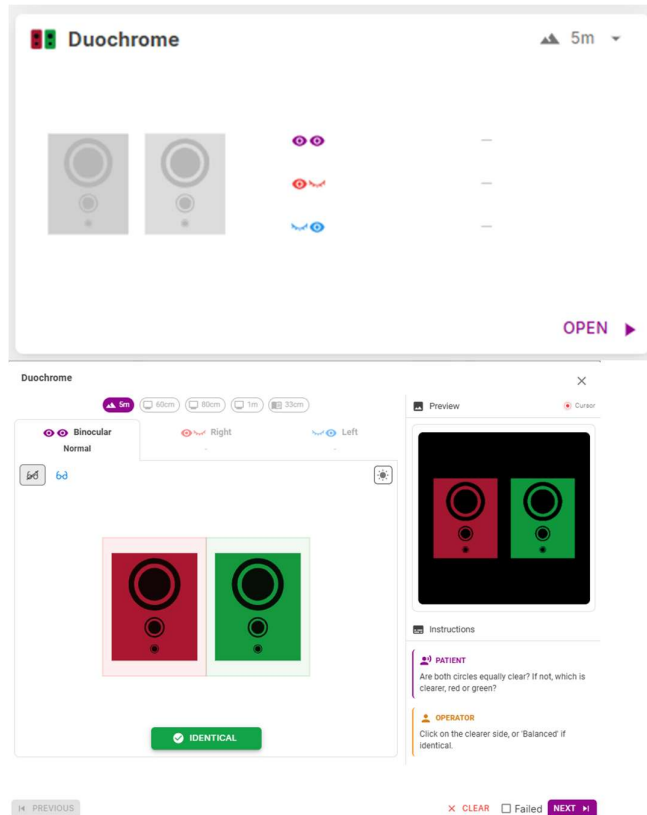


This test is based on the eye's maximum transmission within the red and green wavelengths. These are 620 nm for red and 535 nm for green. These are the wavelengths used for the colors in this test. The dioptric interval between these two values is 0.5 δ . The circular figures on the tests allow the patient to compare their vision against a red background and against a green background.

Execution of the test:

- This test is performed monocularly and then binocularly.
- This test can be performed with or without compensation, depending on what you are looking for: ametropia in the patient or a check on compensation.
- This test should be performed photopically.
- This test is recommended for distance vision in order to limit the patient's accommodation as much as possible.

Description of the VisioWin® interface

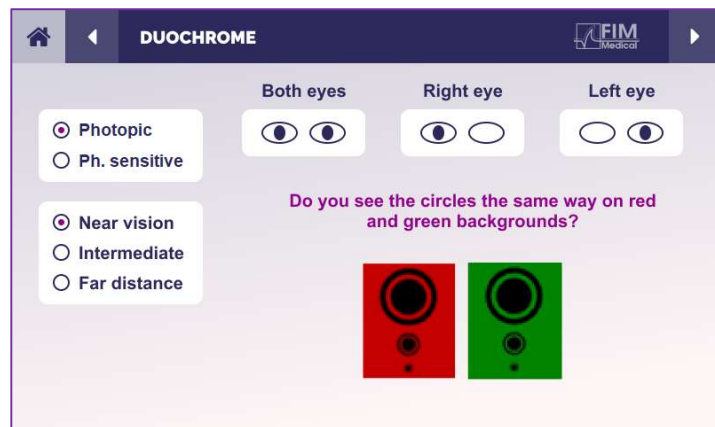


The thumbnail shows the color best perceived by the patient and a possible hyperopic or myopic tendency.

In the response entry window, click on the color that is perceived best.

Click on Identical if the patient does not distinguish a difference.

Description of the Remote-Control interface



The remote-control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Eye being tested
- Question to ask

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: "Are both circles equally clear? If not, which one is clearer, red or green?"

Depth Perception

Purpose and presentation of the test

This test is useful for checking the quality of stereoscopic vision, which is essential for good binocular vision. It is this acuity that enables depth perception and allows the relative distance between objects to be judged. A problem

with stereopsis may reveal certain disorders such as anisometropia, amblyopia, strabismus or image suppression problems. The average stereoscopic threshold for the population is around 40 seconds of arc ("), and any acuity above 60" may indicate a binocular vision problem.

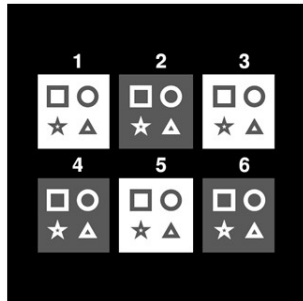


Image seen through the left eye

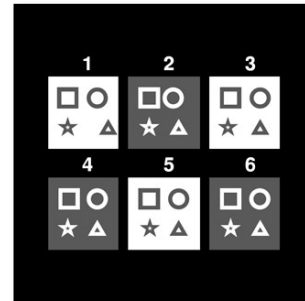


Image seen through the right eye

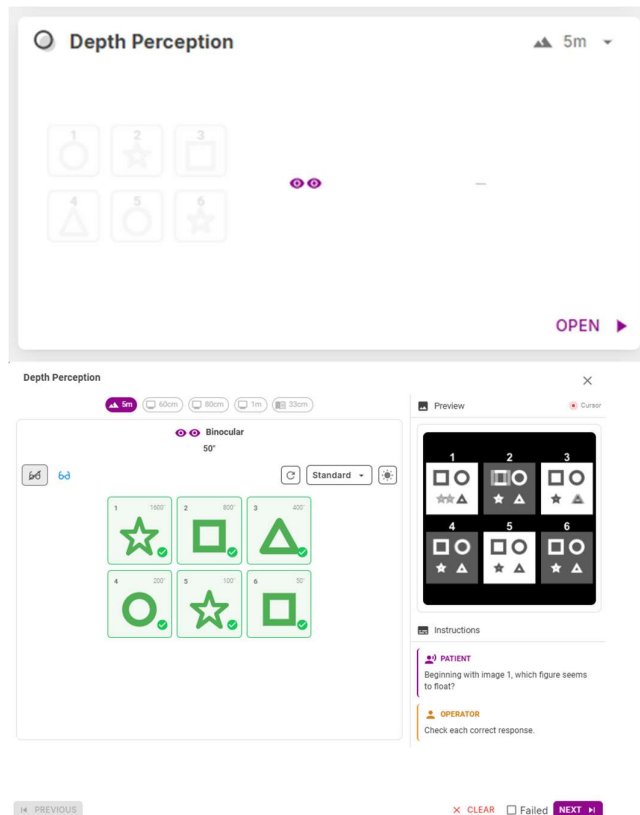
This test consists of six panels, each containing four shapes. In each panel, one of the shapes is shifted to one eye only: the result is that the shifted shape appears in relief to the subject. This is because the brain will try to merge these two virtually identical images. The greater the difference between the position of a shape in the right eye and the left eye, the greater the impression of relief. Fixation disparities are expressed in seconds of arc ("), equivalent to 1/3600th of a degree. They are as follows for this test:

Panel	Shape	Shift between right and left eyes
1	Triangle	1600"
2	Circle	1600"
3	Star	400"
4	Square	200"
5	Star	100"
6	Circle	50"

Execution of the test:

- This test is performed binocularly.
- This test is recommended for both distance and near vision.
- This test must be carried out with the patient's compensation.
- This test should be performed photopically.

Description of the VisioWin® interface

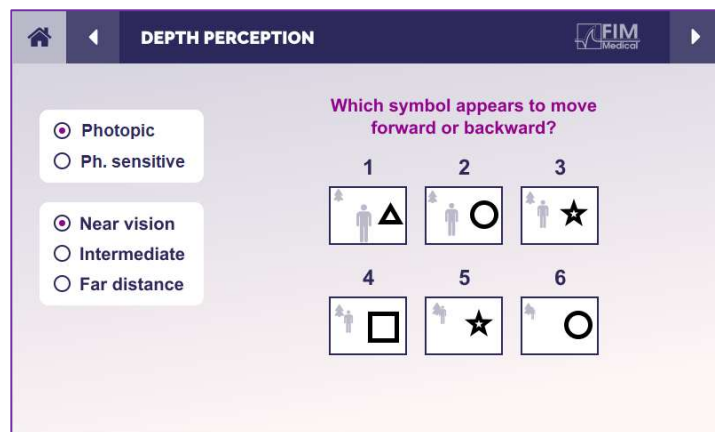


The thumbnail shows the geometric shapes (standard or junior – developed specially for children) perceived in relief by the patient and the corresponding shift level in arc seconds (").

In the response entry window, click on the geometric shapes perceived as shifted, “in relief”, by the patient.

It is not necessary to tick all the boxes independently; selecting the shape with the lowest relief level automatically validates all previous ones.

Description of the Remote-Control interface



The remote control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Question to ask
- Geometric shapes in relief

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: “Starting from figure 1, which figure seems to float?”

Phoria test

Purpose and presentation of the test

The phoria test shows the tendency of an eye to deviate from its binocular fixation position in the absence of a fusional stimulus. It is also known as heterophoria or dissociated phoria, and is measured in prism diopters (Δ). There are several forms:

- An esophoria denotes a crossing of the visual axes in front of the fixed object.
- An exophoria causes these axes to cross behind the object.
- An L/R or R/L hyperphoria occurs when one eye is deviated vertically from the other.
- Incyclophoria or excyclophoria occurs when one eye tends to turn slightly on itself along its anterior-posterior axis.

However, it is not abnormal for a subject not to be orthophoric. In fact, there are categories into which the majority of the population fall without this representing a problem for them.

- The majority of subjects have between 0 Δ and 2 Δ of exophoria in distance vision.
- The majority of subjects have between 0 Δ and 6 Δ of exophoria in near vision.

Poorly compensated phoria can subsequently result in severe visual fatigue, diplopia or even neutralization of the image in one eye. This test achieves complete dissociation of the two eyes because it includes no fusion lock between them.

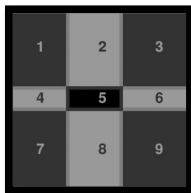
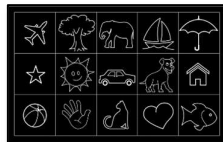


Image seen through the left eye



*Image seen through the left eye
(Child-friendly variant)*

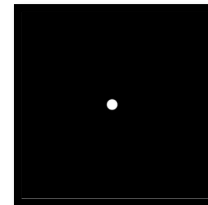


Image seen through the right eye

This test, used to assess a patient's heterophoria, consists of two images. The first is a grid of nine squares, while the second consists of a single dot. This grid will allow the value of the phoria to be framed as follows:

Horizontally:

- Phorias greater than 9 Δ .
- Phorias between 3 Δ and 9 Δ .
- Phorias less than 3 Δ .

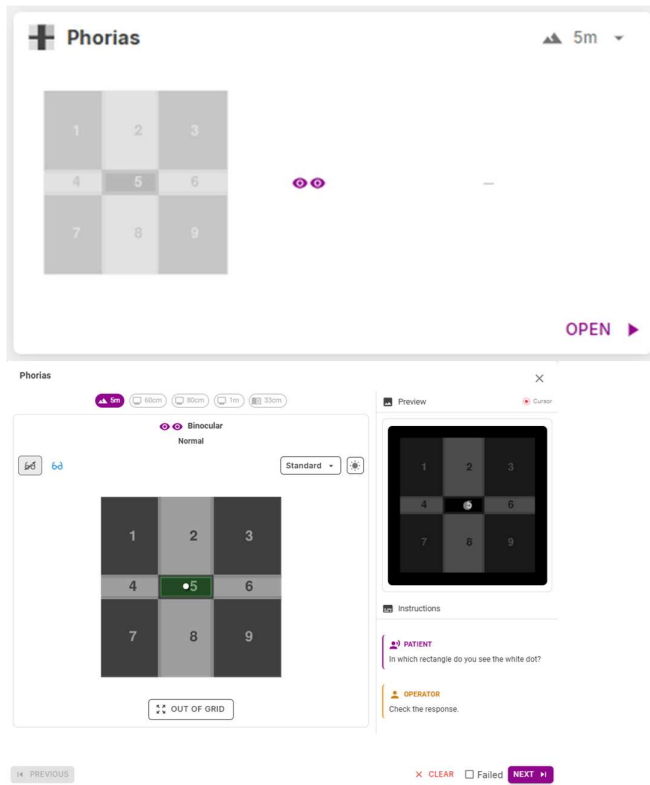
Vertically:

- Phorias greater than 9 Δ .
- Phorias between 1 Δ and 9 Δ .
- Phorias less than 1 Δ .

Execution of the test:

- This test is performed binocularly.
- This test must be performed with the patient's compensation.
- This test can be performed photopically and possibly mesopically.
- This test should be performed when monocular acuity is approximately the same. If the difference is too great, this test will have no diagnostic value.

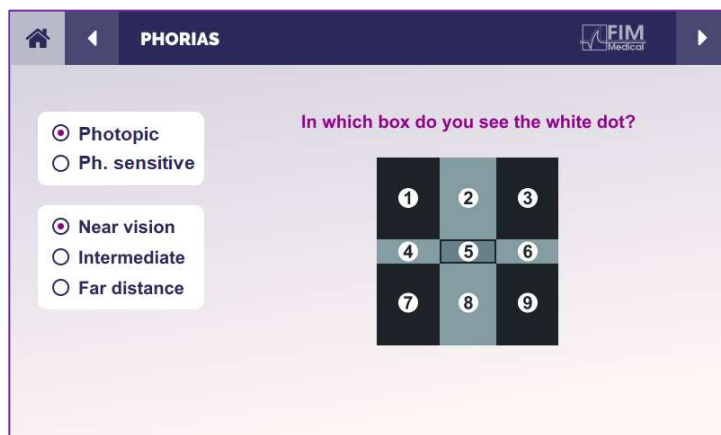
Description of the VisioWin® interface



The thumbnail displays the 9-square grid shown to the patient and the trend associated with the entered result.
The viewing distance can be changed.

In the response entry window, click on the box in which the patient perceives the white dot.
The trend related to the result is displayed above the input grid.
Tick the Out of grid box if the patient does not perceive the white dot.

Description of the Remote-Control interface



The remote-control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Question to ask

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

Ask the following question: "In which box do you see the white dot?"

Fusion test

Purpose and presentation of the test

The purpose of this test is to check the patient's binocular vision. It is known as the Worth test. It will determine whether the patient's brain is able to fuse images from the right eye with those from the left. Fusion requires good visual acuity in each eye. Fusion problems can be more or less advanced, ranging from a disparity in fixation to the complete suppression of one of the two images. They are also often responsible for significant visual fatigue when working on a computer screen.

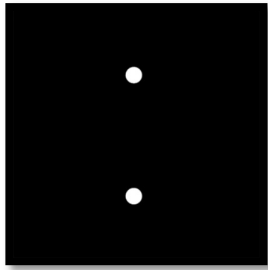


Image seen through the left eye

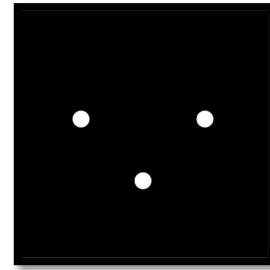


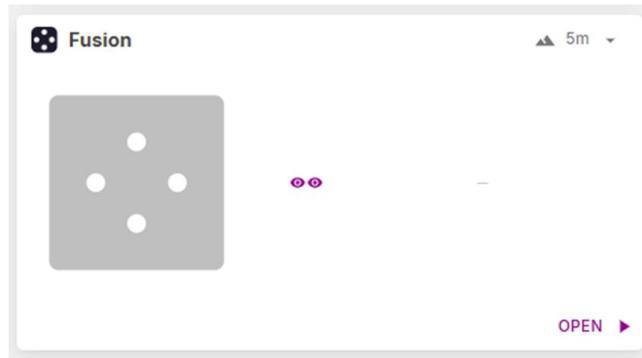
Image seen through the right eye

This test consists of two different images. The image for the left eye contains two dots, while the image for the right eye contains three dots. The lower dot, which is common to both images, must be fused.

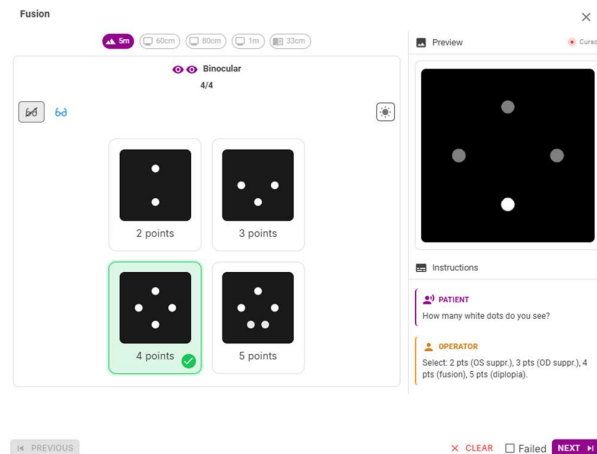
Execution of the test:

- This test is performed binocularly.
- This test must be performed with the patient's compensation.
- This test must be performed photopically.

Description of the VisioWin® interface

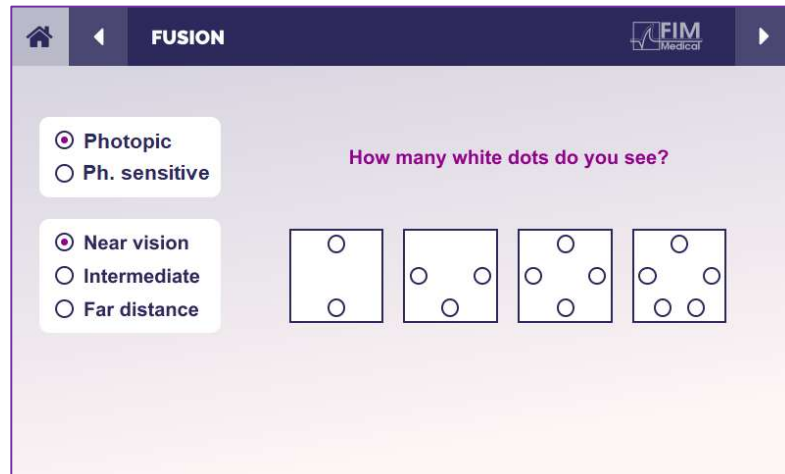


The thumbnail indicates whether fusion is possible or not.
The viewing distance can be changed.



In the response entry window, click on the number of dots perceived by the patient.
The trend related to the result is visible above the input boxes.

Description of the Remote-Control interface



The remote-control interface allows you to view the conditions of the current test:

- Display brightness level
- Viewing distance
- Question to ask

Read the question aloud and note the perceived result on the response form.

Instructions to be given to the patient

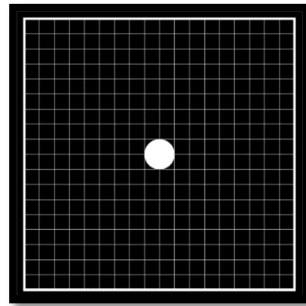
Ask the following question: "How many white dots do you see?"

Amsler grid test

Purpose and presentation of the test

The Amsler grid is a test used to identify vision problems linked to retinal problems and, more specifically, damage to the macula. The purpose of this test is to check the central 20° of the retina. In particular, it is used to detect Age-related Macular Degeneration (AMD), a disease that mainly affects people aged over 50. It is an essential test because it can detect the following pathologies:

- Glaucoma
- Scotoma
- Optic nerve damage
- AMD
- Metamorphopsia
- Peripheral or central field loss

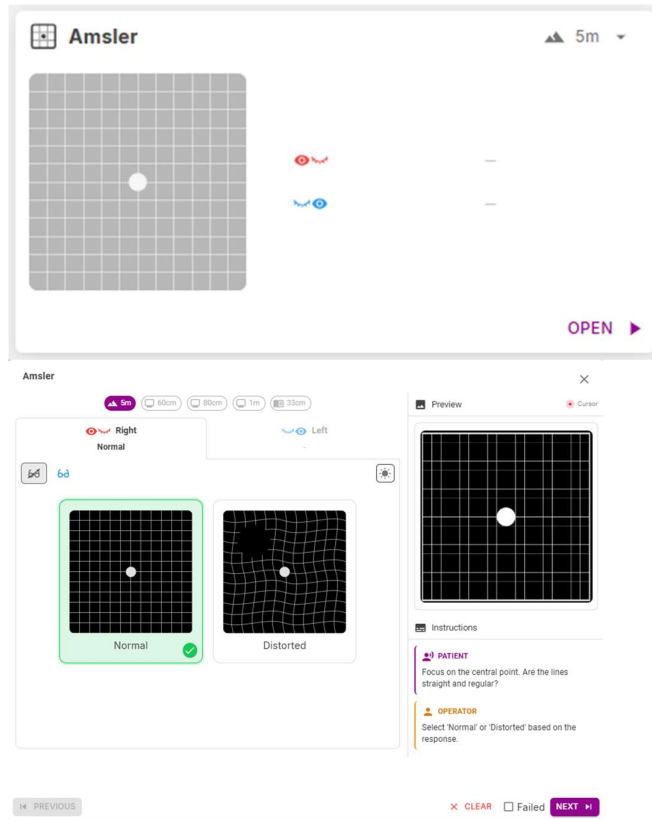


This test was developed by a Swiss ophthalmologist called Marc Amsler. It takes the form of a square grid viewed at an angle of 20°. Each row and column is made up of 20 squares and there is a fixation point in the center of the grid. This will enable the patient's gaze to be fixed so that their visual field can be monitored. We opted for a white grid on a black background, but different versions exist.

Execution of the test:

- This test is performed monocularly.
- This test must be performed with the patient's compensation.
- This test should be performed photopically.

Description of the VisioWin® interface

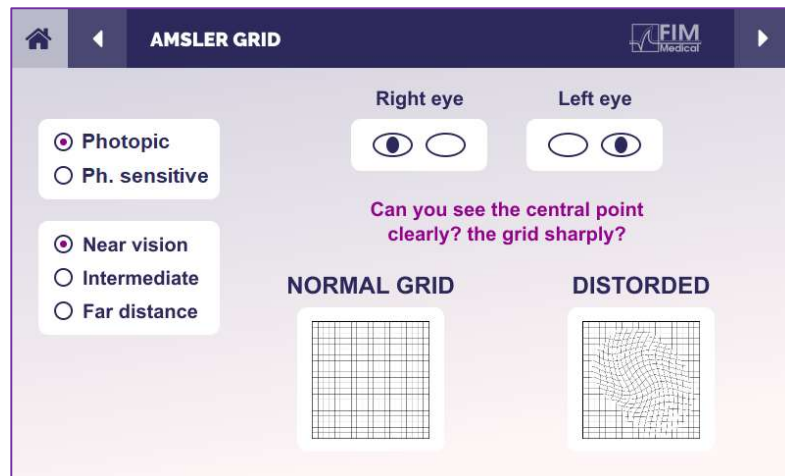


The thumbnail shows the results for each eye tested.

The viewing distance can be changed.

In the response entry window, tick whether the patient perceives the grid as normal or distorted.

Description of the Remote-Control interface



The remote-control interface allows you to view the conditions of the current test:

- Display brightness level
- Eye being tested
- Viewing distance
- Question to ask

Read the question aloud and note the perceived result on the response form.

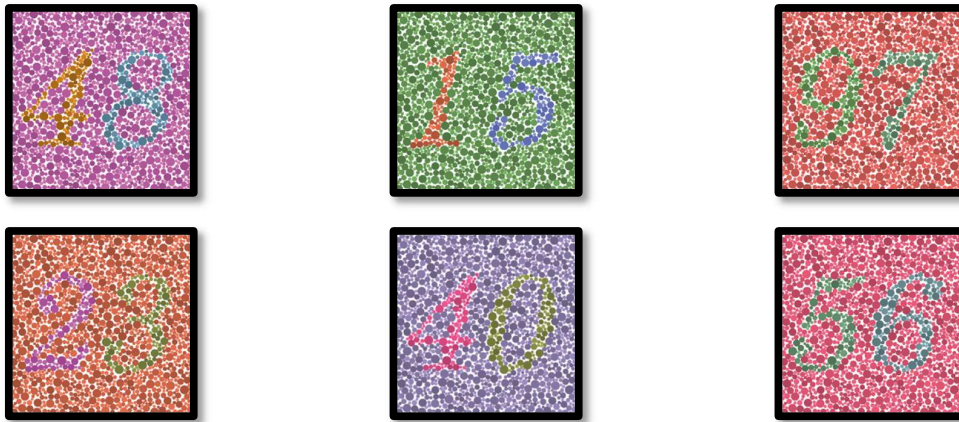
Instructions to be given to the patient

Ask the following question: "Focus on the central point. Are the lines straight and regular?"

Color perception test

Purpose and presentation of the test

This color perception test, consisting of a set of pseudo-isochromatic charts, is used to screen for abnormalities in color vision, principally dyschromatopsias of the Protan, Deutan and Tritan types. By reading the numbers on all the charts, it is possible to determine the state of a subject's color perception. Difficulty in recognizing certain numbers may reveal difficulty in recognizing certain colors.



The color perception test is based on the use of pseudo-isochromatic plates (PIC). The test consists of six number plates using the principle of color confusion lines in the CIE-xy diagram (Commission Internationale de l'Éclairage).

The background and pattern colors are strategically chosen on a line of confusion, so that the pattern is visible to a normal subject, but not to a subject with a color deficiency. Together, these tests make it possible to examine 12 lines of chromatic confusion in the three axes: Protan, Deutan and Tritan.

Each test consists of a mosaic of dots of different colors, shades and dimensions.

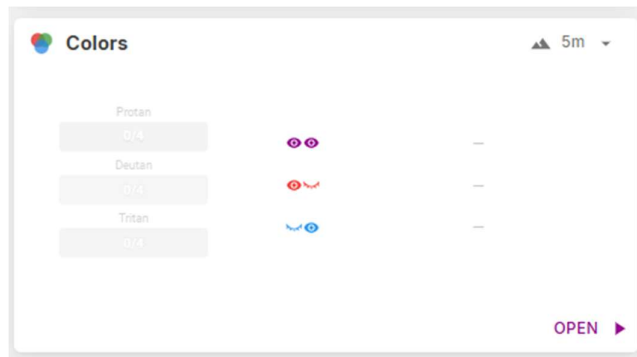
Each plate has 3 different shades (one for the background, one for the 1st digit and another for the 2nd digit).

Each shade is itself made up of several nuances.

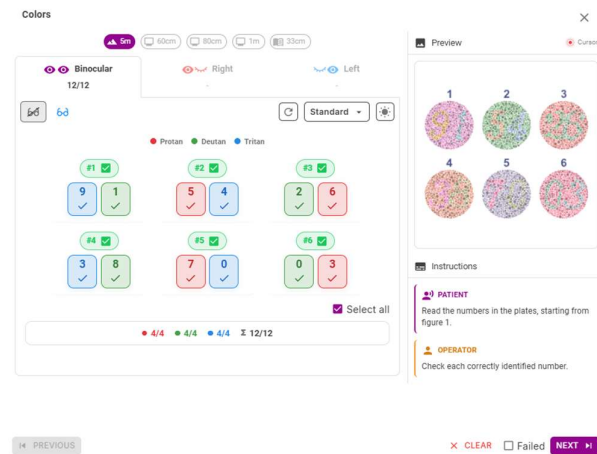
Execution of the test:

- This test is performed binocularly, but can also be performed monocularly.
- This test must be performed with the patient's compensation.
- This test must be performed photopically.

Description of the VisioWin® interface



The thumbnail shows the colored numbers to be identified by the patient for each vision mode.
The check boxes represent the numbers perceived or not perceived by the patient.
The viewing distance can be changed.

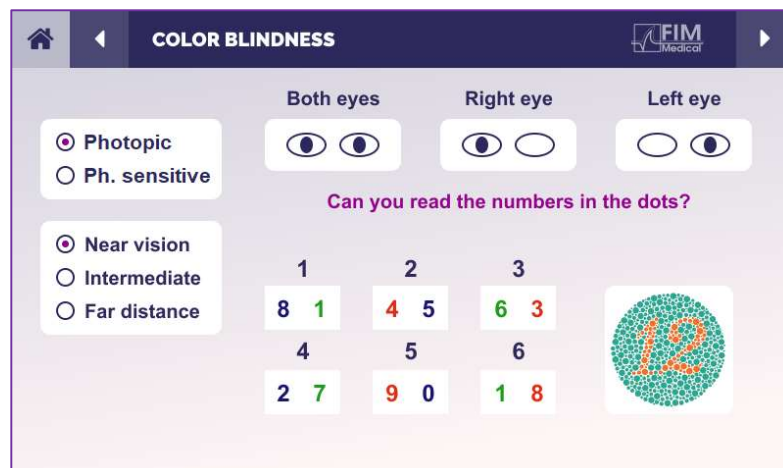


In the response entry window, tick the boxes corresponding to the numbers correctly recognized by the patient.

Tick each digit box individually, or tick the number box above the pair of digits to validate both digits at once.

A running score for the current result is displayed at the bottom of the input grid.

Description of the Remote-Control interface



The remote-control interface allows you to view the conditions of the current test:

- Display brightness level
- Eye being tested
- Viewing distance
- Question to ask

Read the question aloud and note the perceived result on the response form.

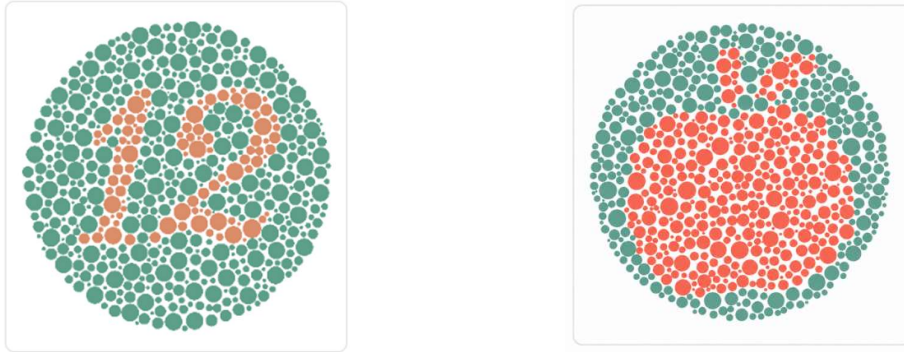
Instructions to be given to the patient

Ask the following question: "Read the numbers on the plates, starting from figure 1."

Ishihara test

Purpose and presentation of the test:

The Ishihara test is one of the most widely used and internationally recognized screening tools for congenital red-green color vision deficiencies (protan and deutan anomalies). It is based on a series of pseudo-isochromatic plates: each plate is made up of a mosaic of colored dots whose hue and saturation are selected along specific confusion lines of the color space, while their size and brightness vary randomly. A digit is formed within the mosaic using dots of a color that a subject with normal color vision can distinguish from the background, whereas a subject with a red-green deficiency will have difficulty perceiving it, will read a different digit, or will perceive nothing at all.



Examples of an Ishihara pseudo-isochromatic plate

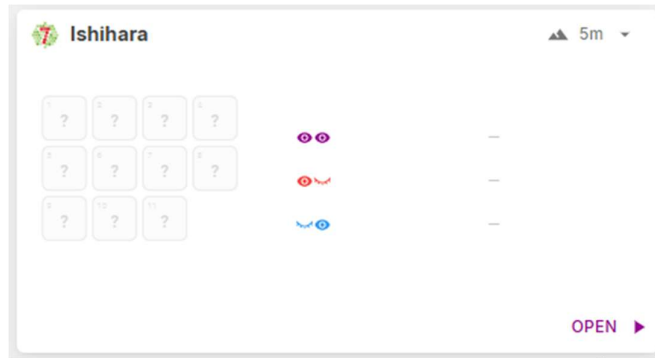
The plate series used in the Visiolite® Flex combines several categories of plates: some are visible to every subject, some are visible only to subjects with normal color vision ("vanishing" plates), and others are specifically designed to differentiate a protan from a deutan deficiency. Based on the pattern of correct, incorrect, and absent responses across the series, the software automatically computes three software-specific indicators for the examination: a Normal-vision score, a Red-Green deficiency score, and an indicator orienting toward a protan deficiency, which together help characterize the type of anomaly detected.

Because it relies solely on red-green confusion lines, the Ishihara test does not evaluate blue-yellow (tritan) deficiencies and does not grade their severity: it is a screening test, and a positive (abnormal) result should be confirmed with a more discriminant test, such as the HRR test.

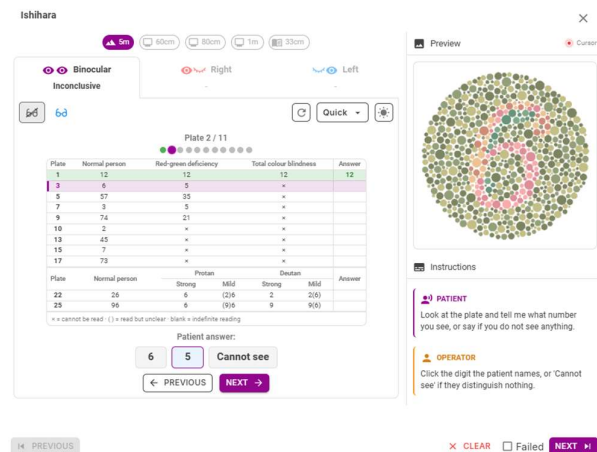
Execution of the test:

- This test can be performed binocularly or monocularly
- It must be performed under photopic (normal) illumination
- This test must be performed photopically.

Description of the VisioWin® interface



After the test, the result is reported in the thumbnail: the score is shown for each response category defined for the test (Normal, RedGreen, Protan), together with the score broken down by vision mode tested (binocular, right eye, left eye).



In the response entry window, click on the digit or figure named by the patient, or click on the "Cannot see" button if the patient does not perceive any digit or figure.

You can monitor the progress of the test using the number of plates left at the top of the response entry window.

Instructions to be given to the patient

Ask the following question: "Look at the plate and tell me what number you see, or say if you do not see anything."

Beyne Lantern Test***Purpose and presentation of the test***

The Beyne Lantern ("Lanterne de Beyne") is a functional color vision test used in occupational medical examinations, in particular for the railway, maritime, and public transport sectors. Unlike pseudo-isochromatic plate tests, which assess the ability to distinguish colored patterns printed on paper or displayed on screen, the lantern test evaluates the practical ability to correctly name colored signal lights under conditions intended to simulate operational signaling: the lights are presented individually, with variations in size, saturation, and luminous intensity, similar to those encountered in railway, maritime, or public transport signaling.

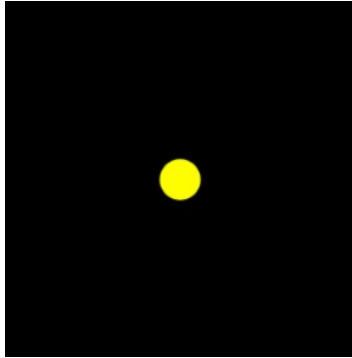


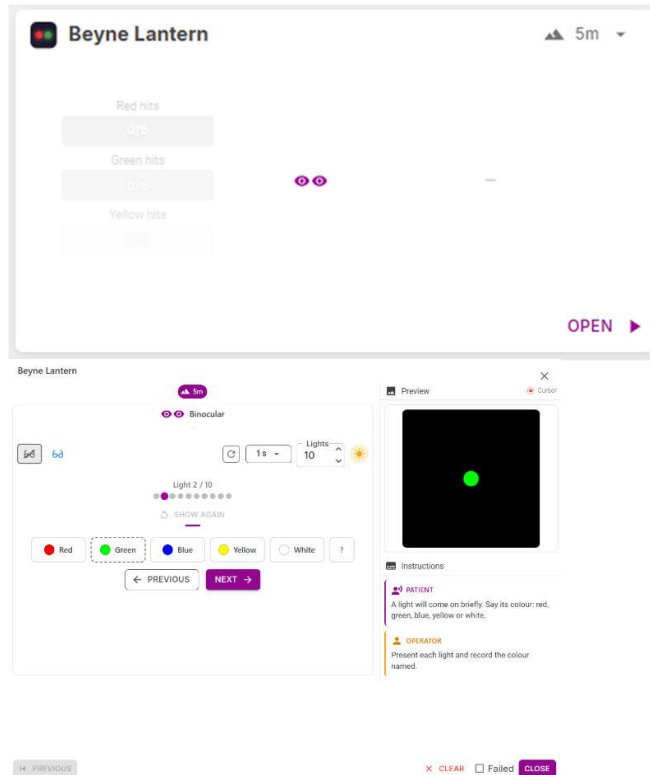
Figure – Signal light as presented to the patient

This type of test is used as a complement to pseudo-isochromatic plate testing because some individuals with a mild congenital color vision deficiency are nonetheless able to correctly name operational signal colors, thanks to compensatory cues such as brightness, saturation, and position. This distinction is important for occupational fitness-for-duty decisions in safety-sensitive professions, where functional color recognition, rather than laboratory plate reading, is the relevant criterion.

Execution of the test:

- This test is performed binocularly only
- It is performed at a fixed viewing distance of 5 meters or 20 feet.
- It can be performed with or without the patient's habitual correction.
- Ambient room lighting should be subdued, so that the projected lights are seen under conditions comparable to night-time signal viewing.

Description of the VisioWin® interface



After the test, the result is reported in the thumbnail as the number of correct responses out of the total number of lights presented and the number of errors. As this test is performed in binocular vision only, no separate right-eye or left-eye score is shown.

Click the start button. Select the light color seen by the patient or ? if the answer is uncertain.

You can monitor the progress of the test using the number of pairs left.

Instructions to be given to the patient

Ask the following question: “A light will come on briefly. Say its color: red, green, blue, yellow or white.”

Köbl Shades of Gray Test

Purpose and presentation of the test

The Köbl Shades of Gray test is an achromatic (grayscale) contrast test used to assess a patient's reading ability under conditions of progressively reduced luminance contrast. Unlike the colored contrast tests offered by the Visiolite® Flex, such as MARS or Landolt, which use letters or rings at fading contrast, this test presents a grid of two-digit numbers printed in shades of gray against a white background: contrast decreases row by row, from clearly legible dark gray digits at the top of the grid to very faint, barely perceptible digits at the bottom.

2	7	8	2	1
23	6	4	32	5
5	4	65	65	46
1	64	32	542	64
46		35	46	63

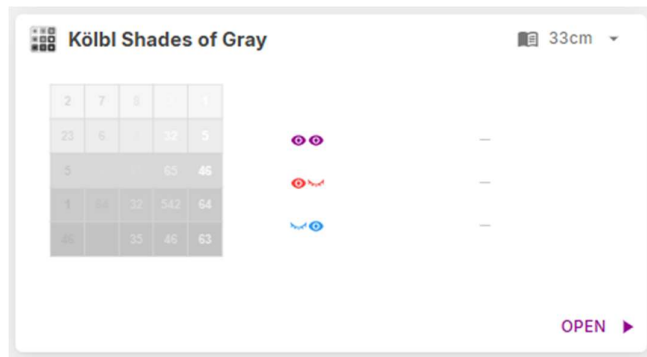
Figure – Shades of Gray grid as presented to the patient

This format provides a rapid, purely luminance-based estimate of contrast sensitivity for near/reading tasks, independent of color discrimination, and is complementary to the letter- and ring-based contrast tests of the device. It is particularly useful in low-vision assessment and for assessing reduced reading contrast sensitivity, which may be associated with cataract, glaucoma, macular disease, or age-related changes — a reduction that may not be captured by a standard visual acuity measurement alone.

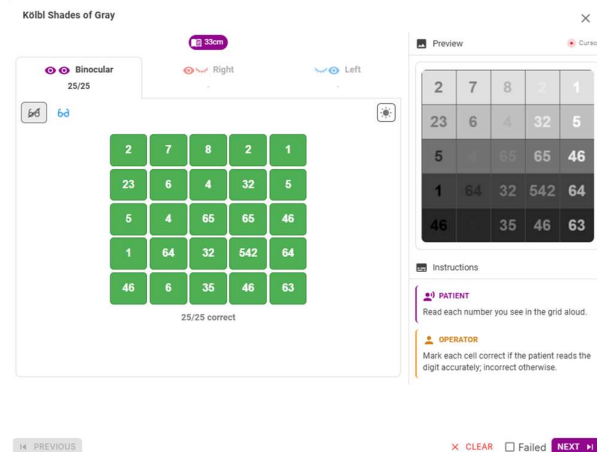
Execution of the test:

- This test can be performed binocularly or monocularly
- It is performed at a fixed near reading distance of 33 cm.
- It must be carried out with the patient's near correction, if any.
- It is generally performed under photopic illumination; a low-photopic setting can optionally be used to assess the effect of reduced ambient lighting on reading contrast sensitivity.

Description of the VisioWin® interface



After the test, the result is reported in the thumbnail as the number of numerals read correctly out of 25, broken down by vision mode tested (binocular, right eye, left eye).



In the response entry window, click each number that the patient reads correctly. A running score is displayed beneath the grid ("x / 25 correct").

Instructions to be given to the patient

Ask the following question: "Read each number you see in the grid aloud."

Glare resistance test

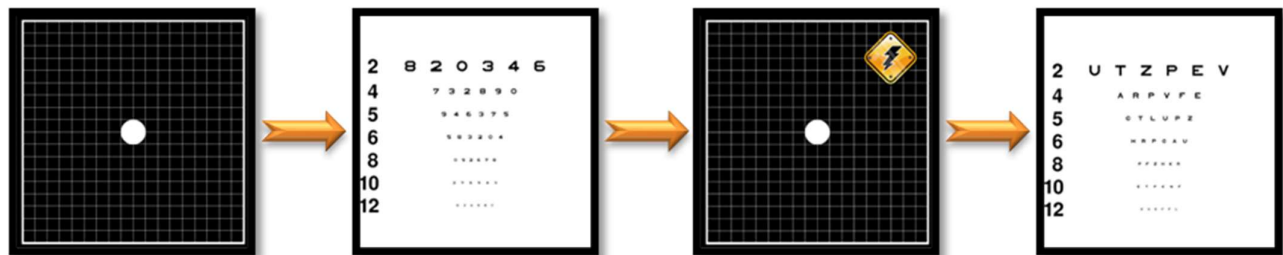


NOTE: The glare resistance test must not be carried out on photosensitive patients who have recently taken photosensitizing medication.

NOTE: Medical contraindications to carrying out this test are detailed in the section on contraindications.

Purpose and presentation of the test

The central glare test is used to check the recovery time of a subject's central vision after intense glare. Some conditions lengthen this time, so this test can be used to detect certain macular impairments in the patient. It is essential to carefully check all contraindications for this test to avoid triggering adverse reactions in the patient. It is also important to clearly warn the patient about the relatively high intensity of the light.



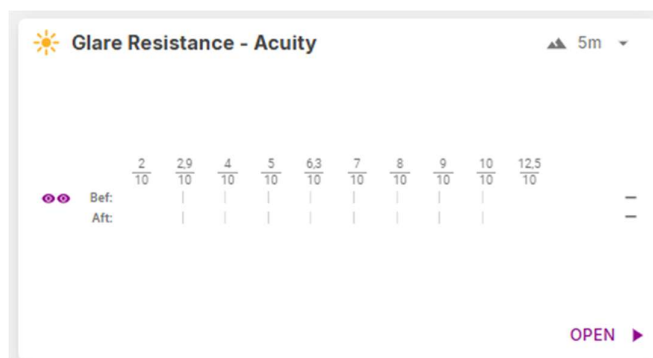
This test uses several other Visiolite® Flex tests. It consists of four steps:

- Step 1. The Amsler grid is presented to the patient under mesopic illumination (3 cd/m²).
- Step 2. An acuity test with numbers is then presented in a mesopic environment.
- Step 3. The patient is then exposed to a glare light of 3 lux.
- Step 4. An acuity test with letters is finally presented in a mesopic environment.

Execution of the test:

- ✓ This test is performed binocularly.
- ✓ This test is performed in distance vision.
- ✓ This test must be performed with the patient wearing their correction.
- ✓ This test must be performed under mesopic conditions.

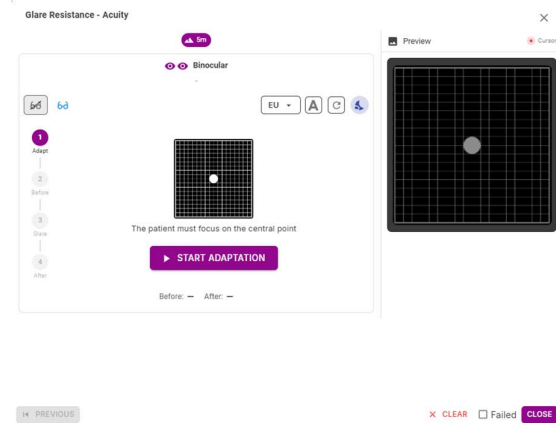
Description of the VisioWin® interface



The thumbnail shows the acuity results before and after glare exposure as well as the recovery time required for the patient to read the smallest line of optotypes after glare. Viewing, distance or lighting conditions cannot be changed for this test.

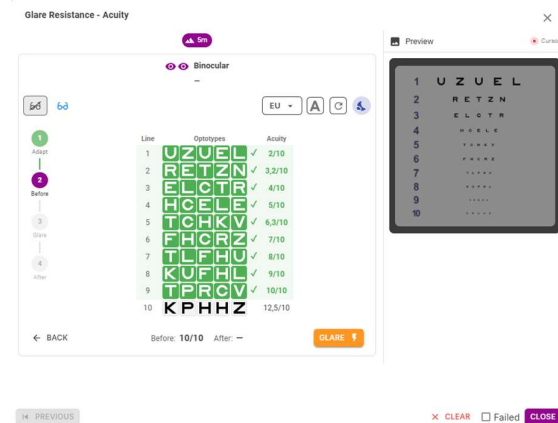
Instructions to be given to the patient

Step 1 – Patient Adaptation



Click on the Start Button. The Amsler grid is displayed at mesopic brightness for 10 seconds.

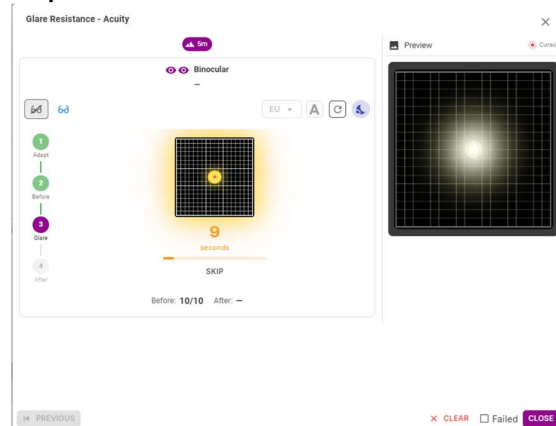
Step 2 – Acuity before glare



Ask the patient to read the optotypes on the smallest line possible.

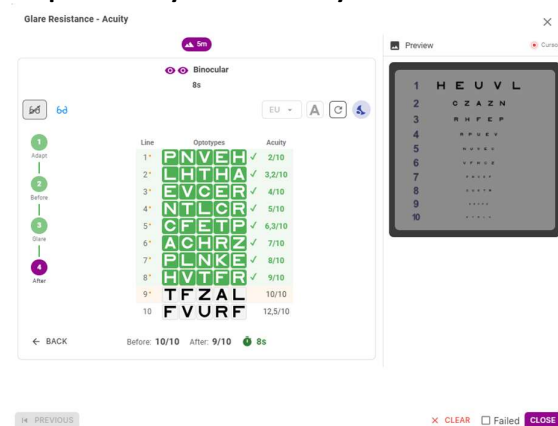
In the response entry window, click on each optotype perceived or on the acuity number of the line to validate the acuity if the minimum validation threshold of optotypes has been successfully recognized by the patient.

Step 3 – Glare



Click on the GLARE button.
Ask the patient to focus their gaze on the central glare point.
The Amsler grid is displayed throughout the 10-second glare duration.
The objective of this step is to induce a scotoma.

Step 4 – Acuity after recovery



Ask the patient to read the optotypes on the smallest line possible as soon as their visual perception has recovered.

A countdown measures the recovery time.
In the response entry window, click on each optotype perceived or on the acuity number of the line to validate the acuity if the minimum validation threshold of optotypes has been successfully recognized by the patient and stop the timer by clicking on the STOP button.
The optotypes displayed are different from step 2 to prevent the patient from memorizing them.

Glare sensitivity test



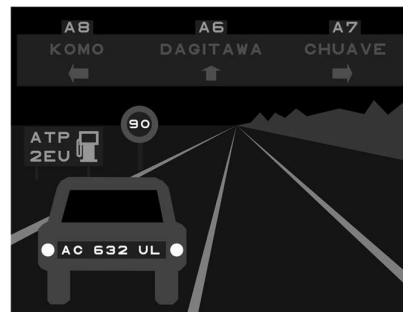
NOTE: The glare sensitivity test must not be carried out on photosensitive patients who have recently taken photosensitizing medication.

NOTE: Medical contraindications to carrying out this test are detailed in the section on contraindications.

Purpose and presentation of the test

Glare corresponds to an excessive light input that the eye cannot tolerate. This phenomenon reduces both comfort and visual performance, and may persist over time even after the glare has ceased.

The purpose of this test is to reveal problems of light sensitivity by presenting a nighttime driving scene where the patient must identify as much information as possible. The more sensitive the patient is, the more the light will appear diffuse and the more difficulty they will have reading information located near the light source. This test therefore makes it possible to highlight the visual capacities of a subject exposed to glare. It is essential to carefully verify all contraindications to avoid triggering adverse reactions in the patient. It is also important to clearly warn the patient about the relatively high intensity of the light.



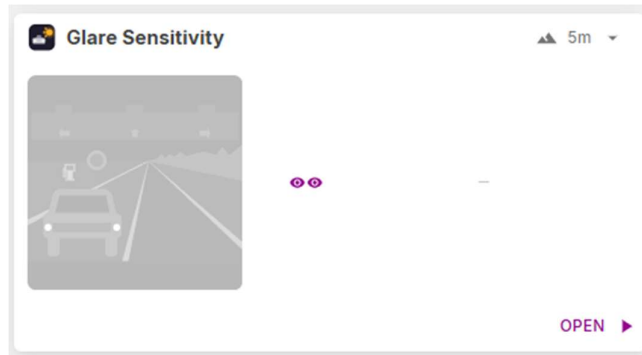
This test represents a nighttime driving scene with a glare source generated by a light-emitting diode positioned on the left-hand side. The scene is composed of six objects that the patient must identify. Each object contains optotypes formed by random letters and/or numbers.

Information to be identified	Contrast level	Decimal visual acuity level
Direction signs	30%	0.32
Information sign	60%	0.32
Speed limit	100%	0.4
License plate	100%	0.4

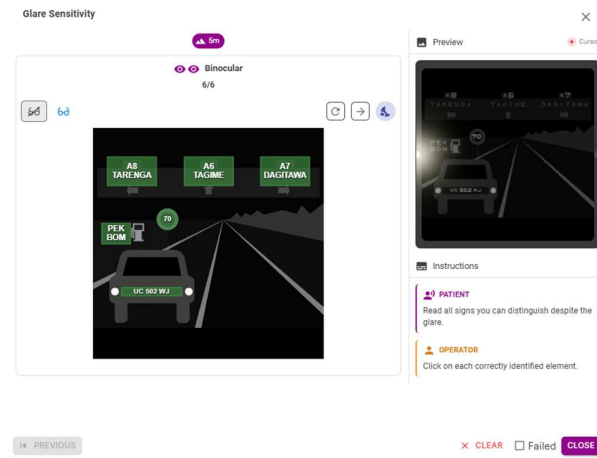
Execution of the test:

- This test is performed binocularly.
- This test is performed at a distance (The vision, distance and lighting conditions cannot be modified for this test.)
- This test must be performed with the patient's compensation.
- This test is performed mesopically.
- The patient must have a visual acuity of at least 4/10 in order to read the displayed information.

Description of the VisioWin® interface



The thumbnail shows the driving scene displayed to the patient; the visual elements perceived are highlighted in green.
The viewing, distance or lighting conditions cannot be modified for this test.



In the response entry window, left-click on the elements perceived by the patient.

In case of an input error, click again on the element to deactivate it.

The selected elements are highlighted in green.
All elements containing letters or numbers can be clicked.

Instructions to be given to the patient

Ask the following question: “Read all signs you can distinguish despite the glare.”

15.Displaying results

Viewing the examination results

Review report

Once the examination is completed, click the Save button to save the examination results. Click the PDF button to generate the examination results in PDF format. The PDF report can then be printed or exported as required.

Vision Examination Report
9/10/2026

bonjour, ceci est un test!

ID: 0BA9AAB9012CD35A
First Name: James
Last name: William
Date Of Birth: 12/31/1998
Sex: Male

Tests and conditions	B	R	L
Astigmatism 5m	—	 Normal	—
Amsler 5m	—	Normal	—

Tests and conditions	B
Acuity 5m	10/10
Contrast Sensitivity 5m	5%
Duochrome 5m	Normal
Depth Perception 5m	50°
Phorias 5m	Normal
Fusion 5m	4/4

Tests and conditions	B
Colors 5m	12/12
Ishihara 5m	Inconclusive
Kölbl Shades of Gray 33cm	25
Glare Resistance - Acuity 5m	Bef: 10/10 Aft: 9/10 Rec: 8s
Glare Sensitivity 5m	6/6

VisioWin 2.1.0 Visiolite Flex SN VLFX260034
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16. Maintenance of the Visiolite® Flex

Cleaning



WARNING: The removable forehead rest, optics and plastic parts of the Visiolite® Flex must be cleaned after each use with a damp cloth and a generic cleaning product authorized by FIM Medical. Only the cleaning efficacy of these products is claimed by FIM Medical.

WARNING: FIM Medical has validated the use of the following pre-soaked wipes or cloths for the treatment of its Visiolite® Flex:

- | | |
|---|--|
| - Clorox® Healthcare Bleach | - Mikrozyd® AF wipes |
| - Clorox® Disinfecting Wipes | - Mikrozyd® Universal wipes premium |
| - Oxivir Excel® Wipes | - Mikrozyd® Sensitive wipes premium |
| - Bactinyl® Disinfecting Wipes | - Aseptonet® Biocide |
| - Sani-Cloth® Bleach / Plus / HB / AF3 | - Anios® Quick wipes |
| - Sani-Cloth Active wipes | - Anios® Excel wipes |
| - Super Sani-Cloth® | - Incidin™ Alcohol Wipe |
| - Formula 409® | - ICB® France Klorxitol |
| - Virex® Plus | - Wipes containing ethanol |
| - Sterimed® 100 | - Wipes impregnated with 70% isopropyl alcohol |
| - PURELL® Healthcare Surface Disinfecting Wipes | - Virex® II 256 |



CAUTION: The device must be cleaned using pre-soaked wipes or cloths only, as direct spraying may allow liquid to enter the housing and damage sensitive electronic components.

CAUTION: Do not immerse the device in liquid or expose it to spraying.

CAUTION: Do not clean the anti-reflective glass window with wet wipes or disinfectant liquids.

CAUTION: The anti-reflective glass window must be cleaned regularly using the supplied microfiber cloth, which is safe for the anti-reflective coating.

CAUTION: If the FIM Medical logo on the removable forehead rest begins to fade, it is recommended to replace the forehead rest.

It is recommended to ask the patient to clean their hands before handling the device.

Cleaning procedure

Cleaning procedure - Visiolite® Flex	
Preparation / disassembly before cleaning	Switch off the device and remove the removable forehead rest from its housing on the front of the device (see "Removable forehead rest" section).
Cleaning	After each patient, wipe/rub the parts accessible to the patient for 10 seconds using the wipe/cloth: - the removable forehead rest (both sides), - the front housing and plastic parts in contact with the patient, - the optics, excluding the anti-reflective glass window (see Caution above). Then respect the contact time (dwell time) recommended by the manufacturer of the cleaning product used, referring to its instructions for use. Note: the anti-reflective glass window must only be cleaned with the supplied dry microfiber cloth, never with wipes or liquid products.
Disinfection	Not applicable (non-critical device; no disinfection is claimed).
Rinsing	Not required.
Drying	Air dry before reuse. Reinstall the removable forehead rest once dry, checking that the FIM Medical logo remains clearly visible.

Periodic maintenance

Annual maintenance of the Visiolite® Flex is recommended for verification of the display and glare LEDs.



CAUTION: Maintenance of Visiolite® Flex can only be carried out by FIM MEDICAL or by a distributor authorized by FIM MEDICAL to carry out maintenance.

Warranty

FIM Medical warrants under normal conditions of use and service that:

Visiolite® Flex is free from defects for a period of 2 years from the date of delivery to the first purchaser.

The contractual guarantee covers repairs only.

The device is guaranteed for 2 years.

Please note that during annual recommended maintenance, a number of preventive operations are performed. However, this maintenance does not constitute a guarantee against potential malfunctions that may arise after the service has been completed.

Service life

FIM Medical estimates the service life of Visiolite® Flex at 10 years subject to proper compliance with cleaning conditions, maintenance and environmental conditions.

No liability for the lack of performance of the device can be attributed to FIM Medical in the event of non-compliance by the user with the maintenance recommendations and conditions of use.

How to return a defective device

In case of a defective device, please contact FIM Medical for support.

Before returning the device, please clean and disinfect it, as explained in the section “Cleaning”.

When sending a device for service, it should be shipped in its original packaging.

Device Disposal

In accordance with the WEEE directive 2012/19/EU, used electronic devices must be treated separately from household waste. The devices must be deposited in specific collection sites (waste disposal centers). For more information, you can contact FIM Medical or your authorized distributor.

	This symbol specifies that this device is considered as electrical equipment and must not be disposed of with household waste. This type of equipment can have potential effects on the environment and human health.
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Glossary

Competent Authority (CA) - National authority responsible for medical device regulation and vigilance in a given country.

Incident - Any malfunction, deterioration in characteristics or performance of a device, or inadequacy in the information supplied.

Malfunction - Failure of the device to perform as intended, without leading to serious consequences.

Manufacturer - Legal entity responsible for the design, manufacture, packaging, and labeling of the device before it is placed on the market.

MDR (Medical Device Regulation) - European Regulation (EU) 2017/745 governing medical devices.

Public Health Threat - Event that could result in widespread risk to public health.

Serious Deterioration of Health - Life-threatening illness or injury, permanent impairment, or medical/surgical intervention required to prevent permanent damage.

Serious Incident - Incident meeting the criteria defined above (death, serious deterioration of health, or serious public health threat).

Trend Reporting - Reporting of statistically significant increase in frequency or severity of non-serious incidents.

User information

Incident Reporting

If a **serious incident** occurs in relation to the use of the device, it shall be promptly **reported to the Manufacturer** using the contacts below and to the **Competent Authority** of the country where the incident occurred.

A **serious incident** is any incident that directly or indirectly led, might have led, or might lead to:

- death of a patient, user, or other person,
- temporary or permanent serious deterioration of a patient's, user's, or other person's state of health,
- a serious public health threat.

If a serious incident occurs in relation to the use of the device, it must be reported:

- to the Manufacturer using the contact details provided below, and
- to the Competent Authority of the country where the incident occurred.

The following reporting timelines apply:

- **Immediately (no later than 2 days)** after awareness of an incident that led to death or serious deterioration of health,
- **Within 15 days** after awareness of any other serious incident.

Malfunctions or incidents that do not result in serious consequences should also be reported to the Manufacturer. Repeated occurrences or increasing frequency of such events may require reporting as trends.

Other User Assistance Information

For other information and requests for technical support, please contact your local distributor using the contacts below.

 MANUFACTURER: FIM MEDICAL 51 rue Antoine Primat 69100 Villeurbanne FRANCE Tel: +33 4 72 34 89 89 Fax: +33 4 72 33 43 51 contact@fim-medical.com www.fim-medical.com	TECHNICAL ASSISTANCE / LOCAL DISTRIBUTOR (Contacts and/or company's stamp)
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Other information

User manual in paper format

A paper version of this user manual is available on request from FIM Medical within 7 days (see support section above).

Declaration of conformity

The present device is classified as a class I medical device according to the European Regulation MDR 2017/745. The device has been designed in accordance with the requirements of IEC 60601-1.

17. Troubleshooting and error messages

Issue	Probable cause	Solution
Visiolite® Flex does not turn on	Power supply fault	Ensure the power cable is securely connected to the device and power source. The power LED must light up after the first press. If using a power strip, try connecting the power supply directly to a wall outlet. Verify that the outlet provides power (test with another device).
The device switches off or goes into standby unexpectedly.	Standby delay set too short in the Visiolite® settings in the software	Increase the standby time via the Visiolite® information screen in VisioWin®.
The device connected via Ethernet (RJ45) does not appear in VisioWin	The device has not been added to the LAN WHITELIST (Settings > Devices) (the firewall is not the cause)	Add the device using the “LAN WHITELIST” button in Settings > Devices
Test display is distorted or inconsistent.	Connection or display issue	For wired mode: - Check the cable integrity. Unplug and reconnect the cable. Also check for signs of screen or graphics controller failure.
Stains are visible on the tests.	Optical or display contamination, possibly due to dust, fingerprints, or other residues	Gently clean the anti-reflective glass window using a dry microfiber cloth. Avoid using alcohol or wet wipes, which may damage the coating. Rotate the optical barrel through all test distances several times. This may help dislodge internal dust particles.
The test display flickers.		
The colors of the tests appear abnormal.	Damaged or unstable screen display	Turn off the Visiolite® Flex, unplug the power supply. Leave the Visiolite® Flex at rest for several hours before plugging it back in.
The brightness is not uniform or is too low.		
The tests appear blurry	The optics are foggy	Clean the anti-reflective glass window with a microfiber cloth.
Some tests are not launched with VisioClick® accessory.	This is not a malfunction: this test is not compatible with VisioClick® automated mode.	Perform this test in manual mode only.
The patient cannot hear the voice prompts with VisioClick® accessory.	Headphones not plugged in properly, Multi Voice Instruction volume set to 0	Check the volume in the Multi Voice Instruction settings.
No update window / Update button not found	This is normal behavior if “Automatically download and install updates” is unchecked: the Update button appears in the upper-right corner at startup	Click “Update” when prompted, or check the box for automatic updates in Settings > General
If the problem persists or for any other problem, contact FIM Medical or your authorized distributor.		

18. Electromagnetic compatibility

The Visiolite® Flex meets the requirements of EN 60601-1-2 regarding the electromagnetic compatibility of medical devices.

Its electronic design ensures robust immunity to surrounding electromagnetic disturbances. As a result, the presence of radio frequency equipment does not affect the reliability of visual screening tests.

The Visiolite® Flex is intended for use in a professional healthcare facility environment and has been tested according to EN 60601-1-2:2015 + A1:2021.

Its emission classification is CISPR 11 Group 1, Class A, according to EN 55011:2016 + A1:2017 + A2:2021.

Electromagnetic emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1 – Complies	The Visiolite® Flex is classified as CISPR 11 Group 1 equipment.
RF emissions CISPR 11	Class A – Complies	The Visiolite® Flex is intended for use in a professional healthcare facility environment.
Harmonic emissions IEC 61000-3-2	Class A – Complies	The Visiolite® Flex is suitable for connection to the specified mains power supply in a professional healthcare facility environment.
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	The Visiolite® Flex is suitable for connection to the specified mains power supply in a professional healthcare facility environment.

Electromagnetic immunity

Immunity test	IEC 60601-1-2 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) — IEC 61000-4-2	±8 kV contact; ±2, ±4, ±8, ±15 kV air	±8 kV contact; ±2, ±4, ±8, ±15 kV air	Use the device in a professional healthcare facility environment.
Radiated RF electromagnetic fields — IEC 61000-4-3	3 V/m, 80 MHz–2.7 GHz	3 V/m, 80 MHz–2.7 GHz	The Visiolite® Flex is intended for use in a professional healthcare facility environment. Keep sources of RF interference away from the device.
RF wireless proximity fields — IEC 61000-4-3	9–28 V/m, depending on frequency	27 V/m at 385 MHz; 28 V/m at 450 MHz; 9 V/m at 710, 745 and 780 MHz; 28 V/m at 810, 870 and 930 MHz; 28 V/m at 1720, 1845 and 1970 MHz; 28 V/m at 2450 MHz; 9 V/m at 5240, 5500 and 5785 MHz.	Avoid using powerful RF transmitters in close proximity to the device.
Electrical fast transient / burst — IEC 61000-4-4	±2 kV power lines; ±1 kV signal lines	±2 kV power lines; ±1 kV signal lines	Use only the power supply and accessories specified by FIM Medical.
Surge — IEC 61000-4-5	±1 kV line-to-line; ±2 kV line-to-earth	±1 kV line-to-line; line-to-earth not applicable	Use only the power supply and accessories specified by FIM Medical.
Conducted RF disturbances — IEC 61000-4-6	3 V, 150 kHz–80 MHz; 6 V in applicable ISM and amateur radio bands	3 V, 150 kHz–80 MHz; 6 V in applicable ISM and amateur radio bands	Keep RF-emitting equipment away from connected cables where possible.
Power-frequency magnetic field — IEC 61000-4-8	30 A/m, 50/60 Hz	30 A/m, 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a professional healthcare facility environment.

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Voltage dips / short interruptions — IEC 61000-4-11	0% U_T for 0.5 and 1 cycle; 70% U_T for 25 cycles; 0% U_T for 250 cycles	0% U_T for 0.5 and 1 cycle; 70% U_T for 25 cycles; 0% U_T for 250 cycles	Mains power quality should be that of a typical professional healthcare facility environment. If operation is interrupted, restart the device before continuing the examination. If continued operation during mains power interruptions is required, it is recommended that the Visiolite® Flex be powered from an uninterruptible power supply (UPS).
Near magnetic fields — IEC 61000-4-39	65 A/m at 134.2 kHz; 7.5 A/m at 13.56 MHz	65 A/m at 134.2 kHz; 7.5 A/m at 13.56 MHz	Keep sources of strong magnetic fields away from the device.

Guidance: Use only the power supply, accessories and detachable parts specified by FIM Medical. If electromagnetic interference causes abnormal operation, stop the examination and restart the device. Do not use examination results if displayed symbols, letters or images are distorted in a way that could affect the screening result.